EXHIBIT 2
(Part One)

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO ALL CLASS ACTIONS	Judge Patti B. Saris
	FILED UNDER SEAL

FOURTH AMENDED MASTER CONSOLIDATED CLASS ACTION COMPLAINT

AMENDED TO COMPLY WITH COURT'S CLASS CERTIFICATION ORDER

UNREDACTED VERSION

TABLE OF CONTENTS

Plaintiffs, by and through their counsel, upon personal knowledge as to their own acts and beliefs, and upon information and belief as to all other matters based upon the investigations of counsel, allege as follows:

I. INTRODUCTION

1. This case is brought by Plaintiffs as a proposed class action on behalf of consumers, self-insured employers, health and welfare plans, health insurers and other end payors for prescription drugs (the "Class") against certain pharmaceutical companies (referred to as the "Defendant Drug Manufacturers").

2. For the last decade, the Defendant Drug Manufacturers have conspired with others in the pharmaceutical distribution chain, including but not limited to physicians and hospitals (hereafter "medical providers" or "providers"), pharmacy benefit managers ("PBMs") and various publishing entities, to collect inflated prescription drug payments from Plaintiffs and the Class.

3. More specifically, the Defendant Drug Manufacturers report to trade publications a drug price – the Average Wholesale Price (or "AWP") – that for many drugs is deliberately set far above the prices that these drugs are available in the marketplace. The AWPs for these drugs are deliberately false and fictitious and created solely to cause Plaintiffs and the Class members to overpay for drugs. Because all drugs administered under Medicare Part B are priced based on the published AWPs, the Defendant Drug Manufacturers inflate AWP reimbursement rates to enable providers and others to make secret profits through overcharges to patients, their insurers and other end payors. This, in turn, motivates the providers to sell and administer the drugs with the most inflated AWPs, resulting in increased market share and profit for the Defendant Drug Manufacturers and inflated payments for drugs by individual patients (through co-pays or direct payments), health plans and insurers.

4. For drugs reimbursed by Medicare Part B (which generally, but not always, require administration in a provider's office), the health care providers administer the drugs and are reimbursed by Medicare based on the inflated AWP. Thus, the providers benefit by pocketing the "spread" between the AWP and the actual cost that they pay for the drugs, and the Defendant Drug Manufacturers benefit by increasing the sales of their drugs that are covered by Medicare Part B ("Covered Drugs") and by increasing their market share. In some cases, the Defendant Drug Manufacturers also provide chargebacks, rebates, hidden price discounts and/or other unlawful financial inducements, including free samples, to further increase the provider's spread and, therefore, their incentive to prescribe a particular Defendant Drug Manufacturer's product. Those discounts are not used by the Defendant Drug Manufacturers in calculating the published AWPs, resulting in their inflation.

5. The use of AWP is not limited to Medicare reimbursement. Rather, AWP is a benchmark from which hundreds of drug prices are derived in transactions throughout the pharmaceutical distribution chain. For "Part B covered drugs" administered outside of the Medicare Part B context, non-Medicare patients and health plans pay for these drugs based on the inflated AWP with an intermediary (for example, a pharmacy benefit manager) pocketing the "spread" between the AWP and the actual cost that the intermediaries pay for these drugs. And similar to the benefit that the Defendant Drug Manufacturers obtain through the AWP scheme for Part B drugs, the Defendant Drug Manufacturers also benefit from the AWP scheme with respect to these drugs by increasing the sales of their particular AWP-inflated drugs and their market share for those drugs. The use of AWP as a benchmark for reimbursement is also not limited to Part B drugs being administered outside of Medicare, but extends to thousands of other drugs as well. And again, with respect to these non-Part B drugs, it is the end payor, be it a health plan or private insurer, that pays the inflated amount. All others in the distribution chain,

be they wholesalers, pharmacies or pharmacy benefit manufacturers, benefit from the spread between AWP and actual costs.

6. Thus, in a perversion of the type of competitive behavior expected in a market not subject to illegal manipulation, the Defendant Drug Manufacturers often promote their drugs not based on lower prices, but by the use of reimbursement rates based on a fictitious and inflated AWP that allows purchasers and intermediaries (including providers and PBMs) to make inflated profits – and the Defendant Drug Manufacturers to increase their market share – at the expense of Plaintiffs and the Class. The Class, as further defined below, consists of all purchasers of drugs whose AWPs were inflated ("AWP End Payor Class").

7. The Defendant Drug Manufacturers also caution providers and other intermediaries that the success of the high profit scheme will be jeopardized if anyone discloses the significantly lower prices actually paid for the drugs (allowing the scheme to be concealed and to continue). All Defendants actively conceal, and caused others to conceal, information about the true pricing structure for the prescription drugs, including the fact that the AWPs for the drugs are deliberately overstated. And, all those in the distribution chain also conceal the rebates, free samples, educational grants and other economic rewards which they receive, but which are not reflected in calculating AWP.

8. In response to the Court's Order on the motion to dismiss, plaintiffs have prepared a list of each of the specific drugs that are the subject of the claims herein. This list is attached as Exhibit A to the Complaint. The drugs identified in Exhibit A will be referred to herein as the AWP Inflated Drugs ("AWPID" or "AWPIDs"). And, in Appendix A, plaintiffs identify the AWP that is the subject of this Complaint for each drug currently at issue pursuant to this Court's Order. Appendix B details which AWPIDs were purchased by each plaintiff.

II. JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under the laws of the United States, 18 U.S.C. § 1964(c), and because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961-1968. The Court also has diversity jurisdiction on Counts IX and X pursuant to 28 U.S.C. § 1332(a) as there is diversity between plaintiff Board of Trustees of Carpenters and Millwrights of Houston and Vicinity Welfare Trust Fund and each Defendant, and the amount in controversy exceeds $75,000. Those claims are asserted only on behalf of this plaintiff as the named plaintiff.

10. The Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367. To the extent necessary, the District Court should retain jurisdiction over all parties pursuant to 28 U.S.C. § 1367 as the claims against all parties are related to the claims upon which original jurisdiction is based.

11. A substantial part of the events or omissions giving rise to the claims in this action occurred in this judicial District, and Defendants may be found within this judicial District. Venue is proper in this jurisdiction under 28 U.S.C. § 1391 and 18 U.S.C. § 1965. Defendants implemented their fraudulent marketing scheme in this District, as well as nationwide, through providers and sales representatives who reside or transact business in this District and thereby affected Class Members, who similarly reside or transact business in this District.

12. The Judicial Panel on Multidistrict Litigation has, by Order dated April 30, 2002, ordered all related cases in the *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, MDL Docket Number 1456, transferred to the District of Massachusetts for coordinated or consolidated pre-trial proceedings.

III. PARTIES

A. Plaintiffs

13. With the exception of the Public Interest Group Plaintiffs, each of the Plaintiffs identified below have, upon information and belief, were charged for the drugs noted based on a formula incorporating AWP.

1. Proposed Class 1 Representatives (Medicare Part B Beneficiaries)

14. Plaintiff Leroy Townsend is a resident of Naples, Florida. During the time period relevant to this Complaint, he was a Medicare recipient who took Zoladex and paid a 20% co-payment.

15. Plaintiff Susan Aaronson resides in Matthews, North Carolina. Mrs. Aaronson, the wife of a local minister, is a Medicare beneficiary with supplemental insurance coverage through her church. Mrs. Aaronson lives with breast cancer and is currently being treated for ovarian cancer. During the applicable time period, Ms. Aaronson was prescribed, and was charged for, the following physician-administered drugs, based in whole or in part on AWP: albumin ~~(manufactured by co-conspirators Aventis Group and~~ Baxter), albuterol sulfate (Dey, the GSK Group, and the Schering-Plough Group), ~~bacitracin (Pfizer), bupivacaine (Abbott)~~, carboplatin injectable ~~(Baxter~~, the BMS Group), cefazolin sodium ~~(Baxter,~~ and the GSK Group), cisplatin (Baxter, the BMS Group, ~~and the Sicor Group~~), darbepoetin alfa (Amgen), dexamethasone sodium phosphate (~~Baxter~~, the Fujisawa Group, ~~the Sicor Group,~~ and Watson), dextrose injectable (Abbott, AstraZeneca, and Baxter), dextrose sodium chloride (Abbott), ~~diltiazem hydrochloride injectable (Abbott, Baxter and the Sicor Group~~), ~~diphenhydramine injectable~~ (~~Baxter, Pfizer, and the Pharmacia Group), enoxaparin sodium (the Aventis Group),~~ epinephrine (~~Abbott~~, Dey ~~and the Sicor Group~~), epoetin alfa (the Johnson & Johnson Group and Amgen), ~~famotidine~~ (~~Abbott and Baxter~~), fentanyl citrate (Abbott, AstraZeneca, ~~Baxter~~, and the Johnson & Johnson Group), furosemide (Abbott, ~~the Aventis Group, and Baxter),~~ glycopyrrolate injectable (~~Abbott, Baxter~~, ~~the Sicor Group,~~ and the Wyeth Group), heparin sodium (Abbott,

Baxter, ~~Pfizer~~, ~~and the Pharmacia Group),~~ hetastarch sodium chloride injectable (~~Baxter and the~~ BMS Group), hydromorphone injectable (~~Abbott,~~ AstraZeneca ~~and Baxter),~~ ipratopium bromide (Dey), lidocaine hydrochloride injectable (~~Abbott,~~ AstraZeneca ~~and Baxter),~~ magnesium sulfate injectable (~~Abbott and the Sicor Group~~), ~~midazolam hydrochloride (Abbott, Baxter and Hoffman-La Roche)~~, morphine sulfate injectable (~~Abbott,~~ AstraZeneca and the BMS Group), ~~neostigmine methylsulfate (Abbott, Baxter, and the Sicor Group~~), odansetron (the GSK Group), paclitaxel, (the BMS Group), pegfilgrastim (Amgen), ~~phenylephrine (Baxter and the Sicor Group~~), plicamycin (Bayer), ~~potassium chloride~~ (~~Abbott and Baxter~~), ~~promethazine injectable (Abbott, Baxter, the Sicor Group, and Watson),~~ ~~ringers lactated with dextrose injectable~~ (~~Abbott and Baxter~~), propofol injectable (~~Abbott,~~ AstraZeneca, ~~Baxter~~, ~~Pfizer, and the Sicor Group~~), sodium chloride (Abbott, ~~the Aventis Group,~~ Baxter, the Schering-Plough Group, ~~and the Sicor Group~~), succinylcholine chloride injectable ~~(Abbott)~~, ~~and vecuronium bromide injectable (Abbott, Baxter and the Sicor Group~~). To date, Mrs. Aaronson has paid several thousands of dollars for these and other prescription drug medications. Although Mrs. Aaronson had supplemental insurance coverage, the coverage required her to make percentage co-payments. Mrs. Aaronson is a proposed class representative for, ~~among other defendants,~~ ~~Aventis~~, Baxter, BMS, Dey, Fujisawa, GSK, Johnson & Johnson, ~~Sicor~~ and Watson.

16. Plaintiff Harold Carter resides in Austin, Texas, and is a 74 year-old, retired wholesale florist. He is a Medicare beneficiary who currently receives partial assistance from Sterling to help defray a portion of his co-insurance obligations under Medicare Part B for his medical care and treatment. Mr. Carter takes prescription drugs for coronary artery disease and other medical conditions, including prostate cancer. During the applicable time period, Mr. Carter was prescribed, and was charged for, the following physician-administered prescription drugs, based in whole or in part on AWP: ~~adenosine (Abbott and Fujisawa),~~ darbepoetin alfa (Amgen), and epoetin alfa (Amgen and the Johnson & Johnson Group). It has been difficult for

Mr. Carter to pay for the high cost of these and other medications, as his supplemental insurance required him to make percentage payments. On a least one occasion Mr. Carter's doctor did not prescribe a medication because Mr. Carter could not pay for it. Mr. Carter is a proposed class representative for ~~Abbott~~, Amgen and ~~Fujisawa~~.

17. Plaintiff Roger Clark is representing the estate of his father, David E. Clark. Mr. Clark resided in Tonto Basin, Arizona, and was a Medicare beneficiary with secondary insurance through the Operating Engineers American Benefit Plan. Berfore he died, Mr. Clark was treated for prostate cancer and inoperable brain cancer. During the applicable time period, Mr. Clark was prescribed, and was charged for, ~~among others,~~ the following physician-administered prescription drugs, based in whole or in part on AWP: cefazolin (~~Baxter~~, the BMS Group, and GSK), cefotetan disodium (the BMS Group), ciprofloxacin hydrochloride (~~Abbott, Baxter,~~ Bayer, and the Schering-Plough Group), cisplatin (Baxter, the BMS Group, ~~and the Sicor Group~~), dexamethasone acetate (Watson), dexamethasone sodium phosphate (~~Baxter~~, Fujisawa, ~~the Sicor Group,~~ and Watson), dextrose injectable (Abbott, AstraZeneca and Baxter), ~~enalaprilat injectable~~ (~~Abbott, Baxter and the Sicor Group~~), epoetin alfa (Amgen and the Johnson & Johnson Group), etoposide (Bedford, Genesia), ~~famotidine~~ (~~Abbott and Baxter~~), fentanyl citrate (Abbott, AstraZeneca, ~~Baxter~~, and the Johnson & Johnson Group), granisetron (the GSK Group and Hoffman-LaRoche), hetastarch sodium chloride injectable (~~Baxter and the~~ BMS Group), hydromorphone injectable (~~Abbott,~~ AstraZeneca ~~and Baxter),~~ ~~labetalol injectable~~ (~~Abbott and Baxter~~), lidocaine hydrochloride injectable (~~Abbott,~~ AstraZeneca ~~and Baxter),~~ ~~methylsulfate (the Fujisawa Group),~~ ~~midazolam hydrochloride (Abbott, Baxter and Hoffman-La Roche),~~ morphine sulfate injectable (~~Abbott,~~ AstraZeneca and the BMS Group), ~~potassium chloride~~ (~~Abbott, Baxter and Pfizer~~), ranitidine (the GSK Group), and sodium chloride (Abbott, ~~the Aventis Group,~~ Baxter, the Schering-Plough Group, ~~and the Sicor Group~~). Mr. Clark has made payments for the foregoing drugs totaling nearly $10,000.00 to date, as his supplemental insurance required him to

make percentage payments for his drugs. Mr. Clark is a proposed class representative for, ~~among other defendants,~~ Abbott, ~~Aventis~~, Baxter, GSK, J&J and ~~Sicor~~.

18. Plaintiff Robert Howe resides in Mapleton, Oregon, and is a 79 year-old Medicare beneficiary, with supplemental insurance coverage through United Health Care of Utah. Before he died, Mr. Howe was treated for prostate cancer. During the applicable time period, Mr. Howe was prescribed, and was charged for, ~~among others,~~ the following physician-administered drugs, based in whole or in part on AWP: dexamethasone sodium phosphate (~~Baxter~~, the Fujisawa Group, ~~the Sicor Group,~~ and Watson), docetaxel (the Aventis Group), gentamicicin sulfate (Abbott, ~~Baxter~~, the Fujisawa Group, and Watson), goserelin acetate (AstraZeneca), granisetron (the GSK Group and Hoffman-LaRoche), novatrone (Immunex) and pegfilgrastim (Amgen). Mr. Howe has made payments for the foregoing drugs, as his supplemental insurance required him to make percentage payments for his drugs. Mr. Howe is a proposed class representative for, ~~among other defendants,~~ Amgen, AstraZeneca, Aventis, GSK, ~~Sircor~~ and Watson.

19. Plaintiff James Monk resides in Lake Village, Arkansas and is a 81 year old Medicare recipient with supplemental insurance. During the applicable time period, Mr. Monk was prescribed, and was charged for, ~~among others,~~ the following physician-administered drugs, based in whole or in part on AWP: casodex (AstraZeneca), ~~eligard (Aventis).~~ Mr. Monk has made payments for the foregoing drugs, as his supplemental insurance requires him to make percentage payments. ~~Mr. Monk is a proposed class representative for, among other defendants, Aventis.~~

20. Plaintiff James Shepley resides in Reno, Nevada, and is an 85 year-old Medicare beneficiary, with secondary insurance coverage through United American. Mr. Shepley is living with prostate cancer. During the applicable time period, Mr. Shepley was prescribed, and was charged for, the following physician-administered prescription drugs, based in whole or in part on AWP: epoetin alfa (Amgen and the Johnson & Johnson Group), goserelin acetate

(AstraZeneca). Mr. Shepley has made payments for the foregoing drugs. Although Mr. Shepley had supplemental insurance coverage, the coverage required him to make percentage co-payments. Mr. Shepley is a proposed class representative for, ~~among other defendants,~~ AstraZeneca and J&J.

21. Plaintiff Larry Young is representing the Estate of Patricia K. Young, his late wife. Before she died, Mrs. Young resided in Enid, Oklahoma where her husband still resides. She was a Medicare beneficiary as a result of a longstanding disability, with supplemental insurance through United Healthcare that covered only a portion of her co-insurance obligation for prescription drugs under Medicare Part B. She received medication for rheumatoid arthritis, Hepatitis C, and lymphoma, the disease that ultimately caused her death. During the applicable time period, Mrs. Young was prescribed, and was charged for, ~~among others,~~ the following physician-administered prescription drugs manufactured and sold by the defendant companies, based in whole or in part on AWP: anzemet (Aventis), aristocort (Fujisawa), ~~cytoxan~~ (the BMS Group, ~~Pfizer, and the Pharmacia Group),~~ dexamethasone acetate (~~Abbott,~~ ~~Bayer~~ ~~and~~ Watson), dexamethasone sodium phosphate (~~Baxter~~, the Fujisawa Group, ~~the Sicor Group,~~ and Watson), dolasetron mesylate (the Aventis Group), dopamine hydrochloride (~~Abbott,~~ ~~Baxter~~, and the BMS Group), ~~epirubicin (Pfizer and the Pharmacia Group),~~ epoetin alfa (Amgen), fentanyl citrate (Abbott, AstraZeneca, ~~Baxter~~, and the Johnson & Johnson Group), filgrastim (Amgen), heparin sodium (Abbott, Baxter, ~~Pfizer,~~ ~~and the Pharmacia Group),~~ hydrocortisone sodium succinate (~~Pfizer and the~~ Pharmacia Group), infliximab (the Johnson & Johnson Group), ~~ketorolac tromethamine~~ (~~Abbott and~~ ~~Baxter~~), levofloxacin (~~Abbott and~~ the Johnson & Johnson Group), lidocaine hydrochloride injectable (~~Abbott,~~ AstraZeneca ~~and Baxter),~~ lorazepam injectable (Abbott, Baxter, ~~and Watson~~), methotrexate sodium injectable (~~Baxter~~, Immunex, and the Wyeth Group), ~~midazolam (Abbott, Baxter and Hoffman-LaRoche),~~ moxifloxacin injectable (~~Bayer and~~ the Schering-Plough Group), oprelvekin (the Wyeth Group), ~~promethazine~~ (~~Abbott,~~ ~~Baxter,~~ ~~the~~

~~Sicor Group, and Watson),~~ protonix injectable (the Wyeth Group), solucortef (Pharmacia), triamcinolone acetonide (the BMS Group), vancomycin sulfate (~~Abbott~~, ~~Baxter~~, and Watson), vincristine sulfate (the Pharmacia Group ~~and the Sicor Group),~~ and warfarin sodium injectable (the BMS Group). At various times throughout the course of Mrs. Young's treatment, the Youngs' made payments via credit card to meet their payment obligations to their various medical providers. To date, the Youngs made many payments for the foregoing drugs, as their supplemental insurance requires them to make percentage payments. The Estate of Patricia Young is a proposed class representative for, ~~among other defendants,~~ Abbott, Amgen, Aventis, Baxter, BMS, Fujisawa, J&J, ~~Pfizer, Sicor~~ and Watson.

22. Plaintiff Virginia Newell is representing the Estate of William Newell. Mr. Newell was a resident of Mooresville, North Carolina. Mr. Newell took prescription drug medications for diabetes and osteoparothis. He was a Medicare recipient with supplemental insurance through the American Association of Retired Persons. During the applicable time period, Mr. Newell was prescribed, and was charged for, ~~among others,~~ the following physician-administered drugs, based in whole or in part on AWP: epoetin alfa (Amgen and the Johnson & Johnson Group), viadur (the Johnson & Johnson Group), taxotere (Aventis) and levaquin (the Johnson & Johnson Group). The Newells made payments for the foregoing drugs, as their supplemental insurance did not cover the full cost of their drugs. The Estate of William Newell is a proposed class representative for, ~~among other defendants,~~ Amgen, AstraZeneca, BMS, J&J and Aventis.

23. Plaintiff Oral Ray Roots resides in Wichita, Kansas and is an 82 year old Medicare recipient with supplemental insurance through AETNA. During the applicable time period, Mr. Roots was prescribed, and was charged for, ~~among others,~~ the following physician-administered drugs, based in whole or in part on AWP: albuterol sulfate (Dey, the GSK Group, and the Schering-Plough Group) and ~~depo provera (Pfizer)~~. Mr. Roots has made payments for

the foregoing drugs because his supplemental coverage required him to make payments for them. Mr. Roots is a proposed class representative for, ~~among other defendants,~~ Dey, ~~Pfizer~~ and Schering-Plough.

24. Plaintiff Hunter G. Walters resides in Bandalia, Michigan and is a Medicare recipient with no supplemental insurance. Mr. Walters receives medication for emphysema and prostate cancer. During the applicable time period, Mr. Walters was prescribed, and was charged for, ~~among others,~~ the following physician-administered drugs, based in whole or in part on AWP: albuterol sulfate (Dey, the GSK Group, and the Schering-Plough Group) and ipratropium bromide (Dey). Mr. Walters has made payments for the foregoing drugs. Mr. Walters is a proposed class representative for, ~~among other defendants,~~ Dey and Schering Plough.

2. Proposed Class 2 Representatives (MediGap Payors)

25. Plaintiff United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW") is an employee welfare benefit plan and employee benefit plan maintained pursuant to Section 302(c)(5) of the LMRA, and is an employee welfare benefit plan established and maintained pursuant to ERISA, for the purpose of providing health benefits to eligible participants and beneficiaries. UFCW maintains its principal place of business in Cook County, Illinois. During the Class Period, UFCW has been billed for and paid charges for AWPIDs, including: Abbott's sodium chloride, gentamicin sulfate, furosemide, heparin lock flush and dextrose; Baxter's sodium chloride and dextrose; Bedford's leucovorin calcium; Sicor's leucovorin calcium; Pharmacia's methylprednisolone sodium; ~~Aventis' Furosemide;~~ Immunex' leucovorin calcium and Johnson & Johnson's Remicade. UFCW also made payments for drugs outside of the Medicare Part B context based on published AWPs. All of UFCW drugs that are at issue in the Complaint are identified in Appendix B. From December 2000 to the present, UFCW has contracted with a PBM to administer its prescription drug benefit for its beneficiaries. For brand name drugs its contract expressly provides that reimbursement is at

"AWP less 13%." For generic drugs its reimbursement is also based on AWP. Prior to December 2000, UFCW contracted with pharmacies for the payment of purchases of pharmaceutical drugs by its members and beneficiaries at an estimated acquisition cost based on the AWPs (less a specified percentage) published by the manufacturers in Medispan.

26. UFCW's beneficiaries began to and have continued to be reimbursed for their purchases of physician-administered drugs pursuant to UFCW's comprehensive medical expense benefit, its major medical plan. *See* United Food and Commercial Workers Unions and Employers Midwest Health Benefits Plan, P001294-1417. UFCW made payments for physician-administered drugs based on published AWPs. Since November 1, 1994, UFCW's comprehensive medical expense benefit has been administered by Blue Cross Blue Shield of Illinois ("BCBS"). Until January 1, 2005, when BCBS' payments for physician-administered drugs began to be established considering ASP, BCBS' payments were based on a negotiated allowance which was established considering a percentage above AWP. For physician-administered drugs not covered by Medicare Part B, UFCW paid 80% or 85% of BCBS' payments, and the UFCW member paid the remainder. Further, UFCW has made co-payments under Medicare Part B throughout the Class Period. A member's 20 percent co-payment under Medicare Part B is, and has been, an eligible expense under UFCW's plans during the Class Period. If Medicare pays a portion of a Fund member's claim under Medicare Part B, UFCW reimburses the remainder of the claim.

27. For transactions that occurred after October 31, 2004, Plaintiff UFCW is able to determine for which drugs it reimbursed and by how much it reimbursed by performing a computer search of its claims files. Such files also show which of its covered members had an amount due and owing after UFCW made its reimbursement of the claim.

28. Plaintiff Pirelli Armstrong Tire Corporation Retiree Medical Benefits Trust ("PMBT") is a voluntary employee benefits association maintained pursuant to the federal

Employee Retirement Security Act, 29 U.S.C. § 1132, *et seq.*, and to the settlement of a federal court action (Case No. 3:94-0573) brought in the United States District Court for the Middle District of Tennessee against Pirelli Armstrong Tire Corp. ("Pirelli") in the early 1990 s by many Pirelli retirees, for the purpose of providing health and medical bnefits to eligible participants and beneficiaries. PMBT maintains its principal place of business in Goodlettsville, Sumner County, Tennessee.

29. During the Class Period, PMBT also reimbursed its members for portions of pharmaceutical bills (including physician-administered drugs) that were covered in the first instance by Medicare Part B. The plan expressly states that it pays 20 percent of all covered Medicare Part B claims. The fund notified that Medicare Part B has covered a given drug or procedure and has paid 80 percent of the cost. The fund then pays the identified "coinsurance" amount, or 20 percent of the total cost Medicare has paid. Numerous drugs fall into this category. Based on a recent review of a small number of our files, PMBT has determined that, with respect to drugs manufactured by the Track 1 Defendants (Astra-Zeneca, Bristol-Myers-Squibb, Glaxo-Smith-Kline and Johnson & Johnson), PMBT made Medicare co-payments with respect to at least the following drugs: Zovirax (Glaxo Smith Kiline), Zoladex (Astra-Zeneca), Cytoxan (Bristol-Myers-Squibb), and Procrit (Johnson & Johnson). ~~Because the fund is composed of retirees, about two-thirds of whom are eligible for Medicare, and because the search was only of a relatively small number of files, plaintiffs are confident that further investigation will show that other drugs were paid for in the Medicare Part B context with respect to the various companies known in this case as "Track 1" and "Track 2" Defendants. Our investigation is continuing.~~

30. Plaintiff Sheet Metal Workers National Health Fund ("SMW Health Fund") is a Taft-Hartley trust administered pursuant to the requirements of 29 U.S.C. § 186 by an equal number of trustees appointed by labor representatives and union representatives. Its Fund Office

is in Goodlettsville, Tennessee. The SMW Health Fund is also a multiemployer welfare fund subject to ERISA. The SMW Heath Fund provides a Supplemental Medicare Wraparound Plus ("SMW+") program that covers the Medicare Part B co-payments of its beneficiaries. There are over 15,000 retirees and covered beneficiaries who receive benefits under the SMW+ program. During the Class Period, the SMW Health Fund has paid for portions of pharmaceutical bills that were covered in the first instance by Medicare Part B. The drugs for which payments were made include Cytoxan (BMS), Etopophos (BMS), Kytril (GSK), Levaquin (J&J), Nevelbine (GSK), Paraplatin (BMS), Procrit (J&J), Remicade (J&J), Rubex (BMS), Taxol (BMS), Vepesid (BMS) and Zoladex (AstraZeneca), ~~and drugs manufactured by Abbott, Amgen, Aventis, Baxter, Bayer, Dey, Fujisawa, Genesia, Immunex, Pfizer, Pharmacia, Sicor and Watson.~~

31. Plaintiff Blue Cross and Blue Shield of Massachusetts, Inc. ("BCBSMA") is a not-for-profit hospital and medical services corporation organized under the laws of Massachusetts, and has its principal place of business in Boston, Massachusetts and is a proposed class representative for Class 2 as against Track 1 defendants. At all times relevant to this action, BCBSMA has been, and is, licensed to do, and is doing, business in the state of Massachusetts. During the Class Period BCBSMA has made co-payments under Medicare Part B for AWPIDs for Track 1 Defendants, including: BMS's Cytoxan, Etopophos, Rubex, Belnoxane, Paraplantin, Vepesid, and Taxol; GSK's Kytril, Zofran, Zantac, Alkeran, Nalvelbine; Shearing's Procrit and Intron-A; AstraZenaca's Zoladex and Pulmicort; and Johnson & Johnson's Remicade, as part of its medigap insurance product known as Medex.

3. Proposed Class 3 Representatives (TPPs and Consumers for AWP-Based Charges on Physician Administered Drugs Outside of Medicare)

32. UFCW is also a proposed representative for this Class.

33. Plaintiff Board of Trustees of Carpenters and Millwrights of Houston and Vicinity Welfare Trust Fund ("CMHV") is an employee welfare benefit plan and employee benefit plan established and maintained pursuant to Section 302(c)(5) of the Labor Management Relations

Act ("LMRA"), 29 U.S.C. § 186(c)(5), and as defined by §§ 1002(1) and (3) of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001, *et seq*., for the purpose of providing health benefits to eligible participants and beneficiaries. As such, CMHV is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). CMHV maintains its principal place of business at 9555 West Sam Houston Parkway South, Suite 400, Houston, Texas. During the Class Period, Carpenters Welfare Trust Fund has been billed for and paid charges for Covered Drugs and otherwise made payments for drugs outside of the Medicare Part B context based on published AWPs. These drugs are identified in Appendix B. During the period relevant to the complaint, CMHV used an administrator to provide medical and drug benefits to its members. CMHV's administrator contracted directly with a PBM to provide pharmacy services to CMHV participants. By contract, all of CMHV's drug purchases were directly and expressly tied to AWP. CMHV paid for brand named drugs in both the retail and mail order context based on AWP minus a fixed percentage. For generic drugs in the retail context CMHV paid based upon MAC, which itself was tied to AWP and in the mail order context CMHV's generic purchases were made at either MAC or AWP minus a fixed percentage. By contract, the AWP used to determine prices was based on that published by "First Databank Blue Book."

34. Plaintiff Teamsters Health & Welfare Fund of Philadelphia and Vicinity ("THWF") is an employee welfare benefit plan and employee benefit plan established and maintained pursuant to Section 302(c)(5) of the LMRA, and is an employee welfare benefit plan established and maintained pursuant to §§ 1002(1) and (3) of ERISA, for the purpose of providing health benefits to eligible participants and beneficiaries. As such, THWF is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. 1132(d). THWF maintains its principal place of business at Fourth & Cherry Streets, Philadelphia, Pennsylvania 19106. It provides comprehensive health coverage for over 28,000 participants and beneficiaries in parts

of Pennsylvania, New Jersey and Delaware. During the Class Period, THWF has been billed for and paid charges for AWPIDs. THWF also made payments for drugs outside of the Medicare Part B context based on published AWPs. All drugs covered by this Complaint purchased by this plaintiff are identified in Appendix B. THWF uses the services of a PBM to administer its prescription drug program. Based upon its contracts it pays for brand name drugs at AWP minus a fixed percentage, and pays for generics based on MAC, which is itself based on AWP. It also pays for certain drugs outside the PBM context and does so based on AWP.

35. Plaintiff Twin Cities Bakery Workers Health and Welfare Fund ("TCBW") is a jointly administered Taft-Hartley Fund established and maintained pursuant to Section 302(c)(5) of the LMRA, and is an employee welfare benefit plan established and maintained pursuant to ERISA, for the purpose of providing health benefits to eligible participants and beneficiaries. TCBW maintains its principal place of business in Eagan, Minnesota. As such, TCBW is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). TCBW provides health benefits, including prescription drug benefits, to approximately 2000 active participants, and their spouses and dependants. During the Class Period, TCBW has been billed for and paid charges for AWPIDs. TCBW also made payments for drugs outside of the Medicare Part B context based on published AWPs. The drugs purchased by TCBW at issue in this litigation are identified in Appendix B. TCBW contracts with a third-party administrator for administration of its pharmacy and medical benefits programs. This administrator in turn contracts with pharmacies and reimburses the pharmacies based upon published AWPs. For example, a typical agreement with a pharmacy providing services to TCBW members provides that reimbursement is at "AWP minus 10%." It further provides that the AWP is determined by Medispan. As for generics, reimbursement is based on MAC, which in turn is derived from AWP.

36. Plaintiff Philadelphia Federation of Teachers Health and Welfare Fund ("PFTHW") is a voluntary employee benefits plan organized pursuant to § 501(c) of the Internal

Revenue Code for the purpose of providing health benefits to eligible participants and beneficiaries. PFTHW maintains its principal place of business in Philadelphia, Pennsylvania. PFTHW provides health benefits, including prescription drug benefits, to approximately 20,000 active participants, and their spouses and dependents. During the class period, PFTHW has been billed for and paid charges for covered drugs and otherwise made payments for drugs outside of the Medicare Part B context based on published AWPs. These drugs are identified in Appendix B. During the period relevant to this Complaint PFTHW used a PBM to provide prescription services for its members. At all times its payment formula for both brand name and generic drugs was expressly tied to AWP.

37. Plaintiff Man-U Service Contract Trust Fund ("Man-U Service Fund") is a trust fund established and maintained pursuant to Section 302(c)(5) of the Labor Management Relations Act, 29 U.S.C. § 186(c)(5), and is an employee benefit plan established and maintained pursuant to the Employee Retirement Income Security Act, 29 U.S.C. § 1001, *et seq.*, for the purpose of providing health benefits, including prescription drug coverage, to eligible participants and beneficiaries. The Man-U Service Fund maintains its principal place of business at 4600 Powder Mill Road, Suite 100, Beltsville, Maryland 20705. The Manu-U Service Fund provides comprehensive health coverage, including prescription drug coverage, for approximately 1,200 participants and beneficiaries located in Maryland, Delaware, Virginia, North Carolina, Pennsylvania and Washington, D.C. All of Man-U Service Fund's drugs at issue in the Complaint are identified in Appendix B. Plaintiff Man-U Service Fund utilizes the services of a PBM and all of its contracts provide that its drug purchases are directly based on AWP. For example, for drugs purchased through the pharmacy, its contract provides for payment at "AWP – 16%," and for mail-order drugs, "AWP – 23%."

38. BCBSMA is also a proposed representative for Class 3 as against Track 1 defendants. During the Class Period, BCBSMA made payments for drugs outside of the

Medicare Part B context based on published AWPs from Track 1 Defendants. All of BCBSMA drugs that are at issue in the Complaint are identified in _____. BCBSMA contracts to reimburse providers based on fee schedules generated by BCBSMA which fee schedules relating to physician administered drugs are based on the AWP for those drugs.

39. ~~Pipefitter's Local Union 357 ("Pipefitters") is an employee welfare benefit plan and employee benefit plan maintained pursuant to Section 302(c)(5) of the LMRA and is an employee welfare benefit plan established and maintained pursuant to ERISA, for the purpose of providing health benefits to eligible participants and beneficiaries. Pipefitters maintains its principal place of business in Allston, Massachusetts. During the Class Period, Pipefitters has been billed for and paid charges for AWPIDs outside of the Medicare Part B context based on published AWPs. All of Pipefitters drugs that are at issue in the Complaint are identified in Exhibit _____. During the Class Period Pipefitters contracted with a third-party administrator, BCBSMA, to administer its prescription drug benefit for its beneficiaries. Pipefitter's Reimbursement for AWPIDs is based on fee schedules generated by BCBSMA which fee schedules relating to physician administered drugs are based on the AWP for those drugs.~~

40. In addition, from 2002 through 2003, plaintiff William Barnewolt paid out-of-pocket amounts for Procrit (J&J), Arenesp (Amgen), Furosemide (Abbott), and Infed (Watson). Plaintiff William Barnewolt is represented in this action by plaintiff Bonnie Barnewolt, as a successor in interest to William Barnewolt. The amounts Mr. Barnewolt paid were based on AWP. Mr. Barnewolt was a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

41. Plaintiff Cheryl Barreca is a resident of Schaumburg, Illinois. In 1997, 1998, and 2001, Ms. Barreca paid out-of-pocket amounts for Procrit (J&J), Rubex (BMS), Cytoxan (BMS), Kytril (GSK), and Dexamethasone Sodium. Kytril (granisetron HCL) is a physician

administered injectable drug marketed by GSK, which is used to relieve suffering from nausea and vomiting as a result of chemotherapy and radiation therapy. The amounts she paid were based on AWP. Ms. Barreca is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

42. Plaintiff Cynthia Byrski is a resident of Chicago Heights, Illinois. In 2002, Ms. Byrski paid out-of-pocket amounts for Rubex (BMS), Kytril (GSK), Cytoxan (BMS), and Dexamethasone Sodium. The amounts she paid were based on AWP. Ms. Byrski is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

43. Plaintiff Mary Cauble is a resident of Granite City, Illinois. In 2004, Ms. Cauble paid out-of-pocket amounts for Rubex (BMS), Dextrose, Dexamethasone Sodium, and Heparin Sodium. The amounts she paid were based on AWP. Ms. Cauble is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

44. Plaintiff Anna Choice is a resident of Chicago, Illinois. From 2000 through 2005, Ms. Choice paid out-of-pocket amounts for Rubex (BMS), Zofran (GSK), Cytoxan (BMS), Heparin, Dexamethasone Sodium, and Taxotere (Aventis). Taxotere (docetaxel) is a physician administered injectable drug marketed by Aventis, which is used to treat locally advanced cancers following the failure of chemotherapy. The amounts she paid were based on AWP. Ms. Choice is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting co-insurance amounts paid by plan participants, are based on AWP.

45. Plaintiff Joyce Dison is a resident of Toulon, Illinois. In 2000 and 2001, Ms. Dison paid out-of-pocket amounts for Rubex (BMS), Cytoxan (BMS), Dexamethasone Sodium, and Anzemet (Aventis). The amounts she paid were based on AWP. Ms. Dison is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

46. Plaintiff Tracy Garcia is a resident of Oak Lawn, Illinois. In 2004 and 2005, Ms. Garcia paid out-of-pocket amounts for Rubex (BMS), Cytoxan (BMS), Albuterol (Schering-Plough), Neulasta (Amgen), Heparin, Sodium Chloride, Anzemet (Aventis), and Dexamethasone Sodium. The amounts she paid were based on AWP. Ms. Garcia is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

47. Plaintiff Donna Kendall is a resident of Decatur, Illinois. From 2002 to 2004, Ms. Kendall paid out-of-pocket amounts for Cytoxan (BMS), Kytril (GSK), Rubex (BMS), Procrit (J&J), ~~Dexamethasone Sodium,~~ Sodium Chloride, Lorazepam (Abbott), and Taxotere (Aventis). The amounts she paid were based on AWP. Ms. Kendall is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

48. Plaintiff Sandra Leef is a resident of Chicago, Illinois. In 2001, Ms. Leef paid out-of-pocket amounts for Cytoxan (BMS), Dexamethasone Sodium, Anzemet (Aventis), Lorazepam (Abbott), and Fluorouracil (Fujisawa). The amounts she paid were based on AWP. Ms. Leef is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue

Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

49. Plaintiff Gerald Miller is a resident of Peoria, Illinois. In 2004 and 2005, Mr. Miller paid out-of-pocket amounts for Paraplatin and Dexamethasone Sodium manufactured by BMS. The amounts he paid were based on AWP. Mr. Miller is a beneficiary of the UFCW Fund, which is administered by Blue Cross/Blue Shield of Illinois, which charges for physician-administered drugs based on AWP, and any co-payments are based upon AWP.

50. Plaintiff Joseph Miller is a resident of Merrillville, Indiana. In 1997 and 1998, Mr. Miller paid out-of-pocket amounts for Zofran (GSK), Heparin Sodium, Cisplatin (Baxter), Furosemide (Abbott), and Dexamethasone Sodium. The amounts he paid were based on AWP. Mr. Miller is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

51. Plaintiff Constance Nelson is a resident of McHenry, Illinois. In 2000 and 2002, Ms. Nelson paid out-of-pocket amounts for Rubex (BMS), Zofran (GSK), Cytoxan (GSK), Heparin, Procrit and Dexamethasone Sodium. The amounts she paid were based on AWP. Ms. Nelson is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

52. Plaintiff Andrea Palenica is a resident of Oak Lawn, Illinois. In 2000 and 2005, Ms. Palenica paid out-of-pocket amounts for Cytoxan (BMS), Kytril (GSK), Dexamethasone Sodium (Watson), Leucovorin Calcium (Sicor), and Dextrose (Baxter). Upon information and belief, the amounts Ms. Palenica paid were based on AWP. Ms. Palenica is a beneficiary of the UCFW Fund, which is administered by Blue Cross/Blue Shield of Illinois, which has previously

testified that its charges for physician-administered drugs, and the resulting co-insurance amounts paid by plan participants, are based on AWP.

53. Plaintiff Regina Shoemaker is a resident of Crown Point, Indiana. In 1996 and 1997, Ms. Shoemaker paid out-of-pocket amounts for Cytoxan (BMS) and Dextrose. The amounts she paid were based on AWP. Ms. Shoemaker is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

54. Plaintiff Scott Tell is a resident of Freeport, Illinois. In 1999, 2000 and 2004, Mr. Tell paid out-of-pocket amounts for his wife Rhonda's medications, including Kytril (GSK), Paraplatin (BMS), Heparin and Dexamethasone Sodium. The amounts he paid were based on AWP. Mr. Tell is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

55. Plaintiff Kenneth Vanderwal is a resident of Dyer, Indiana. In 2003 and 2004, Mr. Vanderwal paid out-of-pocket amounts for Remicade (J&J). The amounts he paid were based on AWP. Mr. Vanderwal is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

56. Plaintiff Pauline Vernick is a resident of Buffalo Grove, Illinois. In 2002, Ms. Vernick paid out-of-pocket amounts for Cytoxan (BMS), Rubex (BMS), Sodium Chloride, Heparin, Anzemet (Aventis), and Dexamethasone Sodium. The amounts she paid were based on AWP. Ms. Vernick is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

57. Plaintiff Mardolyn Vescovi is a resident of Shorewood, Illinois. In 2002, Ms. Vescovi paid out-of-pocket amounts for Cytoxan (BMS), Rubex (BMS), Procrit (J&J), Heparin, Dexamethasone Sodium and Anzemet (Aventis). The amounts she paid were based on AWP. Ms. Vescovi is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

58. Plaintiff Susan Wessels is a resident of Rock Falls, Illinois. In 2004 and 2005, Ms. Wessels paid out-of-pocket amounts for Zoladex (AstraZeneca). The amounts she paid were based on AWP. Ms. Wessels is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

59. Plaintiff Kathleen Weaver-Zech is a resident of Chicago, Illinois. In 2003, Mrs. Weaver-Zech paid out-of-pocket amounts for Remicade. The amounts she paid were based on AWP. Mrs. Weaver-Zech was a beneficiary of the UFCW Fund, which is administered by Blue Cross Blue Shield of Illinois, whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

60. Rebecca Hopkins resides in North East, Pennsylvania, and is a 49 year-old who has been privately insured through Blue Cross/Blue Shield of Pennsylvania for most of the applicable time period. However, for a portion of her medical care and treatment, Mrs. Hopkins had no insurance coverage and had to pay 100% of the cost of her care, amounting to thousands of dollars, which care included physician-administered drugs for which she paid out of pocket. Mrs. Hopkins received medication for ovarian cancer. During the applicable time period, Mrs. Hopkins was prescribed, and was charged for, the following physician-administered drugs, based in whole or in part on AWP: azithromycin (Pfizer), bleomycin sulfate (the BMS Group and the Pharmacia Group), carboplatin injectable (the BMS Group ~~and Baxter), cefuroxime (Baxter),~~

cisplatin (Baxter, the BMS Group, and the Sicor Group), ~~doxycycline (Pfizer),~~ etoposide phosphate (the BMS Group, the Pharmacia Group, and the Sicor Group), minocycline (the Wyeth Group), paclitaxel (the BMS Group), tamoxifen (AstraZeneca), and vancomycin sulfate (Abbott, Baxter, and Watson). Mrs. Hopkins has made payments for the foregoing drugs. Mrs. Hopkins is a proposed class representative for, among other defendants, BMS.

61. George Baker Thomson resides in Gulfport, Florida, and is a 78 year-old who is privately insured through Wellcare. Mr. Thomson is living with prostate cancer. During the applicable time period, Mr. Thomson was prescribed, and was charged for, the following physician-administered drugs, based in whole or in part on AWP: goserelin acetate (AstraZeneca) and ~~triptorelin pamoate (Pfizer and the Pharmacia Group).~~ Mr. Thomson has made payments for the foregoing drugs. Although Mr. Thomson had insurance coverage, the coverage required him to make percentage co-payments. Mr. Thomson is a proposed class representative for, among other defendants, AstraZeneca.

62. Each of the plaintiffs is either producing complete documentation or is in the process of obtaining medical records.

4. Public Interest Group Plaintiffs

63. Plaintiff Vermont Public Interest Research Group ("VPIRG") has been Vermont's leading watchdog and advocacy group since 1972. It is located at 141 Main Street, Ste. 6, Montpelier, Vermont. During the Class Period, VPIRG's members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers and made inflated payments or co-payments based in whole or in part on published AWPs, and were injured by the illegal conduct alleged herein. For example, Ms. Elizebeth Ryan Cole of Thetford, Vermont, an active VPIRG member, purchased the Johnson & Johnson Group's drug Retin-A based in whole or in part upon the published AWP and Ms. Dawn Taylor of Hinesburg, Vermont, an active VPIRG member, purchased BMS's drug Plavix in whole or in part based

upon Defendants' published AWP. As an unincorporated association, VPIRG has standing to pursue this action under Fed. R. Civ. P. 17(b)(1). VPIRG appears in this action for purposes of seeking declaratory, injunctive and other non-monetary relief pursuant to 28 U.S.C. §§ 2201, 2202, § 16 of the Clayton Act and any other applicable statute.

64. Plaintiff Wisconsin Citizen Action ("WCA") is the state's premiere public interest organization with 53,000 individual members and 250 affiliate organizations. It is located at 1202 Williamson St., Suite B, Madison, Wisconsin. During the Class Period, Plaintiff's members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers and made inflated payments or co-payments based in whole or in part upon the published AWP, and were injured by the illegal conduct alleged herein. For example, Ms. Ida Johnson of Oconomowoc, Wisconsin, and active WCA member, purchased Pfizer's drug Lipitor in whole or in part based upon Defendants' published AWP. As an unincorporated association, WCA has standing to pursue this action under Fed. R. Civ. P. 17(b)(1). WCA appears in this action for purposes of seeking declaratory, injunctive and other non-monetary relief pursuant to 28 U.S.C. §§ 2201, 2202, §16 of the Clayton Act and any other applicable statute.

65. Plaintiff New York StateWide Senior Action Council ("StateWide") is a grassroots membership organization made up of individual senior citizens and senior citizen clubs from all parts of New York State. It is located at 275 State Street, Albany, New York. During the Class Period, StateWide's members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments based in whole or in part upon published AWPs, and were injured by the illegal conduct alleged herein. For example, Ms. Mary Jane Snyder of Clifton Park, New York, an active StateWide member, purchased AstraZenaca's drugs Prilosec and Nexium, BMS's drug Tequin, and Schering's drugs Clarinex and K-Dur based in whole or in part on Defendants'

published AWPs. As an unincorporated association, StateWide has standing to pursue this action under Fed. R. Civ. P. 17(b)(1). StateWide appears in this action for purposes of seeking declaratory, injunctive and other non-monetary relief pursuant to 28 U.S.C. §§ 2201, 2202, §16 of the Clayton Act and any other applicable statute.

66. Plaintiff Citizen Action of New York ("CANY") is a coalition of labor, senior citizen, women's, student, tenant and community organizations that works with community activists for social and economic justice. It is located at 94 Central Avenue, Albany, New York. During the Class Period, CANY's members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefore based in whole or in part on published AWPs, and were injured by the illegal conduct alleged herein. For example, Ms. Marilyn Gourley of Binghamton, New York, an active CANY member, purchased Pfizer's drug Zoloft based in whole or in part upon Defendants' published AWPs. As an unincorporated association, CANY has standing to pursue this action under Fed. R. Civ. P. 17(b)(1). CANY appears in this action for purposes of seeking declaratory, injunctive and other non-monetary relief pursuant to 28 U.S.C. §§ 2201, 2202, §16 of the Clayton Act and any other applicable statute.

67. Plaintiff Citizens for Consumer Justice ("CCJ") is a Pennsylvania nonprofit umbrella organization that promotes affordable, quality health care. It is located at Architects Building, 117 South 17th Street, Suite 311, Philadelphia, Pennsylvania. During the Class Period, CCJ's members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or copayments based in whole or in part on published AWPs, and were injured by the illegal conduct alleged herein. For example, Ms. Patricia Pudyk of Aliquippa, Pennsylvania, an active CCJ member, purchased AZ's drug Nexium in whole or in part based upon Defendants' published AWP. As an unincorporated association, CCJ has standing to pursue this action under Fed. R. Civ. P. 17(b)(1). CCJ appears

in this action for purposes of seeking declaratory, injunctive and other non-monetary relief pursuant to 28 U.S.C. §§ 2201, 2202, § 16 of the Clayton Act and any other applicable statute.

B. Defendants

68. The acts charged in this Complaint as having been done by the Defendants were authorized, ordered, or done by their officers, agents, employees, or representatives while actively engaged in the management of the Defendants' business or affairs.

69. Various other individuals, partnerships, sole proprietors, business entities, companies and corporations, presently unknown to Plaintiffs and not named as Defendants in this Complaint, participated as co-conspirators in the violations alleged in this Complaint and performed acts and made statements in furtherance thereof. Such unknown persons or entities acted as co-conspirators and aided, abetted or participated with Defendants in the commission of the wrongful acts alleged in this Complaint.

1. Abbott

70. Defendant Abbott Laboratories ("Abbott") is an Illinois corporation with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois. Abbott is a diversified health care company that discovers, develops, manufactures, and markets health care products and pharmaceuticals. Abbott's principal businesses are global pharmaceuticals, nutritionals, and medical products. Abbott reported revenues for the year 2000 of approximately $13.7 billion and net earnings of $2.8 billion.

71. Abbott, one of the world's largest pharmaceutical companies, is in the business of manufacturing prescription medications for clinical distribution by Medicare Plan B providers nationwide. The drugs manufactured by Abbott and covered by Medicare Part B include, but may not be limited to: acetylcysteine, acyclovir, amikacin sulfate, calcitriol, cimetidine hydrochloride, clindamycin phosphate, dextrose, dextrose sodium chloride, diazepam,

furosemide, gentamicin sulfate, heparin lock flush, metholprednisolone sodium succinate, sodium chloride, tobramycin sulfate, vancomycin, and zemplar.

72. Abbott is also sued herein in its capacity as a participant in the Together Rx conspiracy.

2. Amgen

73. Defendant Amgen Inc. ("Amgen") is a Delaware corporation with its principal place of business at One Amgen Drive, Thousand Oaks, California. Amgen is a biotechnology corporation that focuses its research and development efforts on drugs related to nephrology, cancer, inflammation, neurology and metabolism. In 2000, Amgen's revenues exceeded $3.6 billion.

74. Amgen is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceuticals that are manufactured by Amgen and covered by Medicare Part B include, but may not be limited to: Epogen® (epoetin alfa) and Neupogen® (filgrastim).

3. AstraZeneca

75. Defendant Zeneca, Inc. ("Zeneca") is a Delaware corporation with its principal place of business at Malvern, Pennsylvania. Zeneca is a wholly owned subsidiary of AstraZeneca, PLC, a limited liability company domiciled in the United Kingdom.

76. Defendant AstraZeneca US is a Delaware corporation with its principal place of business at 1800 Concord Pike, Wilmington, Delaware.

77. Defendant AstraZeneca Pharmaceuticals L.P. is a Delaware corporation, with its principal place of business located at 1800 Concord Pike, Wilmington, Delaware. AstraZeneca Pharmaceuticals L.P. is owned and controlled by AstraZeneca PLC, a public limited liability company domiciled in the United Kingdom.

78. AstraZeneca, PLC, Zeneca, Inc., AstraZeneca Pharmaceuticals L.P. and AstraZeneca U.S. are collectively referred to as "AstraZeneca."

79. AstraZeneca maintains research and development and manufacturing facilities worldwide, including in the United States. AstraZeneca reported annual sales of $16.5 billion in 2001, with an operating profit of $4.2 billion.

80. AstraZeneca manufactures and markets several drugs covered by Medicare Part B including, but not limited to: Zoladex® (goserilin acetate implant), Nolvadex® (tamoxifen citrate), Tomudex® (raltitrexed), and Diprivan® (propofol).

81. AstraZeneca is also sued herein in its capacity as a participant in the Together Rx conspiracy.

4. The Aventis Group (Aventis, Pharma, Hoechst and Behring)

82. Defendant Aventis Pharmaceuticals, Inc. ("Pharma") is a Delaware corporation with its principal place of business located at 300-400 Somerset Corporate Blvd., Bridgewater, New Jersey. Pharma is a wholly owned subsidiary of Aventis, S.A., a company domiciled in France. Pharma is comprised of the U.S. commercial operations of predecessor companies Rhone-Poulenc Rorer, S.A. and Defendant Hoechst Marion Roussel, Inc. ("Hoechst"). Prior to its acquisition by Pharma, Hoechst was a Delaware corporation with its principal place of business located at 10236 Marion Park Drive, Kansas City, Missouri.

83. Pharma's principal business activities are the discovery, development, manufacture and sale of prescription pharmaceuticals in the areas of cardiology, oncology, infectious diseases, arthritis, allergies and respiratory disorders, diabetes and central nervous system disorders. Pharma reported U.S. net sales of approximately $5.8 billion in 2001.

84. Defendant Aventis Behring L.L.C. ("Behring"), located at 1020 First Avenue, King of Prussia, Pennsylvania, formerly did business as Centeon L.L.C., a 50/50 joint venture

between Hoechst and Rhone-Poulenc Rorer, S.A. When Centeon L.L.C.'s parent companies merged to create Aventis in 1996, Behring became its wholly-owned subsidiary.

85. Behring is the plasma protein business of Pharma, producing a line of therapies including coagulation therapies for the treatment of hemophilia, wound healing agents used during major surgical procedures, inhibitor treatments that inhibit the formation of blood clots, immunoglobulins for the prevention and treatment of immune disorders, and plasma expanders for the treatment of a variety of conditions such as shock, burns and circulatory disorders. In 2000, Behring held assets estimated at $1.5 billion.

86. The drugs manufactured by Pharma, Hoechst and Behring (collectively referred to as "The Aventis Group") and covered by Medicare Part B include, but may not be limited to: Anzemet® (dolasteron mesylate), Bioclate® (antihemo factor viii), Gammar® (immune globulin), Helixate® (antihemo factor viii), Humate-P® (antihemo factor viii), Mononine® (antihemo factor ix complex), Monoclate-P® (antihemo factor viii), and Taxotere® (docetaxel).

87. Aventis is also sued in its capacity as a participant in the Together Card Rx conspiracy.

5. Baxter

88. Defendant Baxter International Inc. ("Baxter") is a Delaware corporation with its principal place of business at One Baxter Parkway, Deerfield, Illinois. Baxter manufactures and distributes prescription drugs to clinical administrators. Baxter's annual sales from January 1, 2000 through December 31, 2000 were over $6.8 billion.

89. Defendant Baxter Healthcare Corporation is the principal domestic operating subsidiary of Baxter International. Baxter International and Baxter Healthcare Corporation are collectively referred to as "Baxter."

90. Baxter is a global medical products company that, *inter alia*, develops, manufactures, markets and/or distributes drugs to treat cancer, trauma, hemophilia, immune

deficiencies, infectious diseases, kidney disease and other disorders. Baxter reported a year 2000 sales of $6.9 billion.

91. The drugs developed, manufactured, marketed, sold and/or distributed by Baxter that are covered by Medicare Part B include, but may not be not limited to: albumin, Bebulin® (factor ix complex), Buminat® (human albumin), dextrose, dextrose sodium chloride, Gammagard® (immune globulin), Iveegam® (immune globulin), Holoxan® (ifosfanide), Uromitexan® (mesna), Endoxan® (cyclophosphamide), Hemofil M® (antihemo factor viii), Proplex T® (factor ix complex), Recombinate® (antihemo factor viii), cisplatin, sodium chloride, and diazepam.

6. Bayer

92. Defendant Bayer Corporation ("Bayer") is an Indiana corporation with its principal place of business located at 100 Bayer Road, Pittsburgh, Pennsylvania. Bayer is a wholly owned United States subsidiary of a German corporation, Bayer AG. Bayer's pharmaceutical division is located at 400 Morgan Lane, West Haven, Connecticut.

93. Bayer is a highly diversified health care company whose principal business includes the development, manufacture, marketing, sale and/or distribution of healthcare products and services, including pharmaceuticals. Bayer reported sales in the United States of $10.1 billion in 2001 and $8.9 billion in 1999.

94. Bayer is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. The pharmaceutical drugs manufactured by Bayer and covered by Medicare Part B include, but may not be limited to: Kogenate® (antihemo factor viii), FS/Kogenate® (antihemo factor viii), and Koate-DVI® (antihemo factor viii) and Gamimune® (immune globulin), all used to treat hemophilia, and Gamimune® which is used in the treatment of immunodeficiency and autoimmune disorders.

7. The BMS Group (Oncology Therapeutics; Apothecon)

95. Defendant Bristol-Myers Squibb Co. ("Bristol-Myers") is a Delaware corporation with its principal place of business located at 345 Park Avenue, New York, New York. Bristol-Myers is a multi-national health care company specializing in the manufacturing, marketing and sale of pharmaceuticals and medical devices. For the year 2000, Bristol-Meyers reported revenues of approximately $20 billion and net earnings of $4.7 billion.

96. Defendant Oncology Therapeutics Network Corp. ("OTN") is a Delaware corporation with its principal place of business located at 395 Oyster Point Boulevard, Suite 405, South San Francisco, California. OTN has been a wholly-owned subsidiary of Bristol-Myers since its acquisition in 1996. Prior to 1996, OTN was an independent company. In 2001, OTN reported revenues of over $1.4 billion.

97. OTN is a healthcare services and distribution firm that directly sells Bristol-Myers' infusion oncology drugs and related products to approximately 2,300 office-based oncology practices in the United States. At the time of its acquisition by Bristol-Myers, OTN was the leading distributor of chemotherapeutic drugs and related products for the treatment of cancer. Bristol-Myers paid OTN a commission for marketing and selling its drugs. Both prior to and after Bristol-Myers acquired OTN, Bristol-Myers marketed and sold its drugs directly to medical providers across the country, and thus Bristol-Myers and OTN employed and maintained extensive marketing and sales departments.

98. Defendant Apothecon, Inc. ("Apothecon") is a Delaware corporation with its principal place of business located in Princeton, New Jersey. It is a subsidiary of Bristol-Myers specializing in small to mid-size niche brand and generic products.

99. Bristol-Myers, OTN and Apothecon are collectively referred to herein as the "BMS Group."

100. The BMS Group manufactures and distributes prescription drugs that are clinically distributed by Medicare Plan B providers nationwide. The drugs manufactured by the

BMS Group and covered by Medicare Part B include, but may not be not limited to: Blenoxane® (bleomycin sulfate), Paraplatin® (carboplatin), Cytoxan® (cyclophospamide), Rubex® (doxorubicin hydrochloride), Etopophos® (etoposide), Vepesid® (etoposide), TaxolV (paclitaxel), and Fungizone® (amphotericin B).

101. Bristol-Myers is also sued herein in its capacity as a participant in the Together Rx conspiracy.

102. The BMS Group engages in an organization-wide and deliberate scheme to inflate AWPs. The BMS Group has stated fraudulent AWPs for all or almost all of its drugs including Amikacin Sulfate, Amphotercin B, Bleomycin Sulfate, Cyclophospamide, Vespid (Etoposide), Carboplatin (Paraplatin), Taxol (paclitaxel), and Blenoxane. The specific drugs of the BMS Group for which relief is sought in this case are set forth in Appendix A.

8. Dey, Inc.

103. Defendant Dey, Inc. ("Dey") is a Delaware corporation with its principal place of business at 2751 Napa Valley Corporate Drive, Napa, California. Dey is a unit of Merck KGaA, a German pharmaceutical conglomerate.

104. Dey is a specialty pharmaceutical company that primarily develops, manufactures and markets generic drugs used in the treatment of selected respiratory diseases and allergies. Dey, one of the largest U.S. manufacturers of such pharmaceuticals, had net sales of $266 million in 1998.

105. The drugs manufactured by Dey and covered by Medicare Part B include, but may not be not limited to: albuterol sulfate, acetylcysteine, cromolyn sodium, ipratropium bromide, and metproterenol sulfate.

106. Defendant Dey, Inc. f/k/a Dey Laboratories, Inc. ("Dey") is a corporation organized under the laws of Delaware with its principal offices in Napa, California.

107. Dey is a specialty pharmaceutical company focusing on drug products for respiratory diseased and related allergies. The products it manufactures and publishes AWPs on include: Ipratropium, Bromide; Metapeoterenol Sulfate, and Accuneb.

9. The Fujisawa Group (Fujisawa Healthcare, Fujisawa USA)

108. Defendant Fujisawa Healthcare, Inc. ("Fujisawa Healthcare") is a Delaware corporation with its principal place of business located at Three Parkway North, Deerfield, Illinois, 60015. Fujisawa Healthcare is a wholly-owned subsidiary of Fujisawa Pharmaceutical Co. Ltd., a Japanese corporation. Fujisawa Healthcare focuses its efforts in the therapeutic areas of immuno-suppression and transplantation, cardiovascular care, skin care, oncology, and antifungal and anti-infective treatment.

109. Defendant Fujisawa USA, Inc. ("Fujisawa USA") is a Delaware corporation with its principal place of business located at Three Parkway North, Deerfield, Illinois. Fujisawa USA was a wholly-owned subsidiary of Fujisawa Pharmaceutical Co. Ltd. In 1998, Fujisawa Healthcare assumed responsibility for Fujisawa USA's portfolio of proprietary products

110. The drugs manufactured by Fujisawa Healthcare and Fujisawa USA (collectively referred to as "The Fujisawa Group") and covered by Medicare Part B include, but may not be limited to: Acyclovir Sodium, Dexamethasone Sodium Phosphate, Doxorubicin Hydrochloride, Fluorouracil, Gentamicin Sulfate, Pentamidine Isethionate, and Vancomycin Hydrochloride.

10. The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)

111. Defendant GlaxoSmithKline, P.L.C. ("GlaxoSmithKline") is a public limited company incorporated under the laws of England and Wales, with its corporate headquarters located at 980 Great West Road, Brentford, Middlesex, United Kingdom TW8 9GS. GlaxoSmithKline was created through the December 27, 2000, merger of GlaxoWellcome, P.L.C. and SmithKline Beecham, P.L.C. GlaxoSmithKline's operational headquarters are located at One Franklin Plaza, 16th and Race Streets, Philadelphia, Pennsylvania.

112. Defendant SmithKline Beecham Corporation ("SKB"), a wholly-owned U.S. subsidiary of the former SmithKline Beecham P.L.C., is a Pennsylvania corporation with its principal place of business at One Franklin Plaza, 16th and Race Streets, Philadelphia, Pennsylvania.

113. Defendant GlaxoWellcome, Inc. ("Glaxo"), a wholly-owned subsidiary of GlaxoSmithKline, is a North Carolina corporation with its principal place of business at 5 Moore Drive, P.O. Box 13398, Research Triangle Park, North Carolina. Cerenex Pharmaceuticals ("Cerenex"), a division of Glaxo prior to the merger, was responsible for Glaxo's central nervous system drugs, including Zofran.

114. Defendants GlaxoSmithKline, SKB and Glaxo are referred to collectively as the "GSK Group."

115. The GSK Group is a diversified pharmaceutical company which controls an estimated 7 percent of the world's pharmaceutical market. In 2001, the GSK Group reported pharmaceutical sales of $24.8 billion.

116. The drugs manufactured by the GSK Group and covered by Medicare Part B include, but may not be limited to: Hycamtin® (topotecan hydrochloride), Ventolin® (albuterol) and Zofran® (ondansetron hydrochloride). Pierre Fabré Médicament licenses another Medicare Part B drug, Navelbine® (vinorelbine tartrate), to the GSK Group. SmithKline Beecham P.L.C. manufactured and sold Kytril® (granisteron hydrochloride), another drug covered by Medicare Part B (and a competitor to Zofran®), prior to the merger. To secure regulatory approval for the merger, SmithKline Beecham P.L.C. sold Kytril®'s global rights to the Roche Group in December of 2000.

117. GSK is also sued herein as a member of the Together Rx conspiracy.

11. Immunex

118. Defendant Immunex Corporation ("Immunex"), a wholly owned subsidiary of Defendant Amgen, Inc., is a Washington corporation with its principal place of business at 51 University Street, Seattle, Washington. Immunex is a company that develops products for the treatment of cancer, asthma, rheumatoid arthritis, inflammatory diseases, infectious diseases, and cardiovascular diseases. In 1999, its total revenues were $542 million.

119. Immunex is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceutical drugs that are manufactured by Immunex and covered by Medicare Part B include, but may not be limited to: Leucovorin Calcium, Enbrel® (etanercept), Novantrone® (mitoxane hydrochloride), Leukine® (sargramostim), and Thioplex®(thiotepa).

120. Defendant Immunex has been a wholly owned subsidiary of Defendant Amgen, since Immunex' acquisition in July 2002.

12. The Johnson & Johnson Group (J&J, Centocor, Janssen, NcNeil, Ortho)

121. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. In 2001, pharmaceutical sales represented 45% of J&J's worldwide sales and 19% of its operational growth. J&J is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

122. Defendant Centocor, Inc. ("Centocor") is a Pennsylvania corporation and has been a wholly owned subsidiary of Defendant J&J since its acquisition by J&J in October 1999. Centocor's principal place of business is located at 200 Great Valley Parkway, Malvern, Pennsylvania. Centocor manufactures, markets and distributes prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

123. Defendant Janssen Pharmaceutica Products, L.P. ("Janssen") is a New Jersey limited partnership with a principal place of business located at 1125 Trenton-Harbourton Road,

Titusville, New Jersey 08560. Janssen is a subsidiary of Johnson & Johnson. Janssen is sued for its role in the Together Rx conspiracy.

124. Defendant McNeil-PPC, Inc., is a New Jersey corporation. McNeil-PPC, Inc. is a subsidiary of Johnson & Johnson. McNeil Consumer & Specialty Pharmaceuticals is a division of McNeil-PPC, Inc. and has a principal place of business located at 7050 Camp Hill Road, Fort Washington, Pennsylvania 19034. McNeil-PPC is sued for its role in the Together Rx conspiracy.

125. Defendant Ortho Biotech ("Ortho") is New Jersey corporation and has been a wholly owned subsidiary of Defendant J&J since its formation by J&J in 1990. Ortho's principal place of business is located at 700 U.S. Highway 202, Raritan, New Jersey. Ortho manufactures and distributes prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

126. The drugs manufactured by J&J, Centocor, Ortho, McNeil-PPC and Janssen (collectively referred to as "J&J Group") and covered by Medicare Part B include, but may not be limited to: ReoPro® (abciximab), an anti-blood clotting medication, Retavase® (reteplase), an anti blood clotting agent, Procrit® (epoetin alfa), for the treatment of anemia, Leustatin® (cladribine), for the treatment of leukemia, Orthoclone® (muromonab-CD3), used to prevent organ transplant rejection, Sporanox® (itraconazole), used in the treatment of fungal infections, and Remicade® (infliximab), an anti-inflammatory drug.

13. Pfizer, Inc.

127. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York. Pfizer is one of the largest pharmaceutical companies in the United States, whether measured by number of prescriptions written, revenues, or market capitalization.

128. Pfizer is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceuticals that are manufactured by the Pfizer Group and covered by Medicare Part B include, but may not be limited to: Cerebyx® (fosphenytoin sodium injection), Dilatin® (phenytoin), Diflucan® (fluconazole), Zithromax® (azithromycin), Trovan® (trovafloxacin mesylate), and Unasyn® (ampicillin sodium/sulbactam sodium).

129. In addition to manufacturing and marketing drugs that are reimbursed by Medicare Plan B, the Pfizer Group also manufactures and distributes other named brand drugs for which it publishes, or causes to be published, an AWP in various industry compendia.

14. The Pharmacia Group (Pharmacia and Pharmacia & Upjohn)

130. Defendant Pharmacia Corporation ("Pharmacia") is a Delaware corporation with its principal place of business located at 100 Route 206, North Peapack, New Jersey. Pharmacia was created through the merger of Defendant Pharmacia and Upjohn, Inc. and Monsanto Company on March 31, 2000.

131. Defendant Pharmacia & Upjohn, Inc. ("P&U") is a subsidiary of Pharmacia Corp. In 1995, P&U was formed through the merger of Pharmacia AB and The Upjohn Company. P&U became a global provider of human healthcare products, animal health products, diagnostics and specialty products. In 1998, Pharmacia & Upjohn relocated its global headquarters from the United Kingdom to New Jersey. In September 1999, the company established its global headquarters on a 70-acre campus in Peapack, New Jersey. This site is now the management and pharmaceutical headquarters for Pharmacia.

132. Pharmacia is a highly diversified health care company whose business focuses on the discovery, development, manufacture and sale of a broad and diversified line of health care products and services, including pharmaceuticals, diagnostics and hospital products. Pharmacia's Prescription Pharmaceuticals business segment is involved in researching,

developing, registering, manufacturing and selling prescription pharmaceutical products, including general therapeutics, ophthalmology, and hospital products, which include oncology products and diversified therapeutics. Pharmacia reported sales of $18.1 billion for the fiscal year ended December 31, 2000. Pharmacia also reported $12.0 billion in prescription pharmaceuticals sales for the year 2001, and $10.8 billion in prescription pharmaceuticals sales for the year 2000. Prescription pharmaceuticals sales account for over 85 percent of Pharmacia's overall pharmaceutical sales. According to its Annual Report, Pharmacia's oncology drugs generated more than $1 billion in sales in 2001.

133. The drugs manufactured by Pharmacia and P&U (collectively referred to as "The Pharmacia Group") and covered by Medicare Part B include, but may not be limited to: Adriamycin PFS® (doxorubicin hydrochloride), Adrucil® (fluorouracil), Amphocin® (amphotericin), Aromasin® (bleomycin), Camptosar® (irinotecan hydrochloride), Cleocin Phosphate® (clindamycin phosphate), Neosar ® (cyclophosphamide), Cytosar-U (cytarabine), Depo-Testosterone® (testosterone cypionate), Adriamycin PFS® (doxorubicin HCL), Ellence® (epirubicin HCL), Toposar® (etoposide), Adrucil® (fluorouracil), Solu-Cortef® (hydrocortisone sodium succinate), Idamycin® (idarubicin hydrochloride), Medrol® (methylprednisolone), and Vincasar® (vincristine sulfate).

15. The Schering-Plough Group (Schering Plough & Warrick)

134. Defendant Schering-Plough Corporation ("Schering-Plough") is a New Jersey corporation with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey.

135. Schering-Plough's primary business involves prescription products in core product categories, including allergy and respiratory, anti-infective and anticancer, cardiovasculars, dermatologicals and central nervous systems and other disorders. Schering-Plough's revenues in 2001 totaled $9.8 billion.

136. Defendant Warrick Pharmaceuticals Corporation ("Warrick"), is a Delaware corporation with its principal place of business at 12125 Moya Boulevard, Reno, Nevada. Warrick is a wholly-owned subsidiary of Defendant Schering-Plough and has been since its formation in 1993. Warrick manufactures generic pharmaceuticals.

137. The drugs manufactured by Schering-Plough and Warrick (collectively at times referred to as "The Schering-Plough Group") and covered by Medicare Part B include, but may not be limited to: Proventil® (albuterol sulfate), Integrelin® (eptifibatide), Intron A® (interferon alfa-2b recombinant), and Temodar® (temozolomide). The Schering-Plough Group's Albuterol sulfate sales alone totaled $154 million in 2000.

16. The Sicor Group (Sicor and Gensia)

138. Defendant Sicor, Inc. ("Sicor") is a Delaware corporation with its principal place of business located at 19 Hughes, Irvine, California. Sicor was the result of the 1997 merger between Defendant Gensia, Inc. ("Gensia"), a finished dosage manufacturer, and Rakepoll Holding, a Europe-based supplier of active pharmaceutical ingredients.

139. Sicor markets itself as a vertically-integrated specialty pharmaceutical company with expertise in the development, manufacturing and marketing of injectable pharmaceutical products, primarily used worldwide by hospitals. Sicor's finished dosage products manufacturing operations account for 32% of its total revenue, and is comprised of a portfolio of products that includes oncology, anesthesiology, and critical care. Sicor's 2001 revenues totaled nearly $370 million. According to its website, Sicor operates its business through several subsidiaries.

140. Defendant Gensia Sicor Pharmaceuticals, Inc. ("Gensia Sicor"), a Delaware corporation, is a wholly-owned subsidiary of Sicor with its principal place of business located at 17 Hughes, Irvine, California. Gensia Sicor focuses on acute-care multisource products in the

fields of oncology, cardiology, and anesthesiology. Gensia Sicor's injectable drug business includes more than 60 products.

141. In 1999, Gensia Sicor entered into a sales distribution agreement with Abbott Laboratories under which the two companies formed a strategic alliance for the marketing and distribution of oncology products in the U.S. The agreement was restructured in March 2002. In 1999, Gensia Sicor also amended an earlier agreement with Baxter Pharmaceutical Products, Inc. Notably, Abbott (6%) and Baxter (34%) accounted for nearly 40% of Sicor's total product sales in 2001.

142. The drugs manufactured by Sicor, Gensia, and Gensia Sicor (collectively referred to as "The Sicor Group") and covered by Medicare Part B include, but may not be not limited to: amikacin sulfate and tobramycin sulfate.

17. Watson

143. Defendant Watson Pharmaceuticals, Inc. ("Watson") is a Delaware corporation with its principal place of business at 311 Bonnie Circle, Corona, California. Watson develops, manufactures and markets brand and generic pharmaceuticals. Watson is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

144. The pharmaceuticals manufactured by Watson and covered by Medicare Part B include, but may not be limited to: albuterol sulfate, dexamethasone acetate, diazepam, gentamicin sulfate, iron dextran, testosterone enanthate, vancomycin hydrochloride, and cytarabine.

IV. GENERAL ALLEGATIONS APPLICABLE TO ALL DEFENDANTS

145. The allegations contained herein apply generally to all Defendants.

A. The AWP System

146. There are approximately 65,000 different drug products in the United States market, including different dosages of the same drug. Prescription drugs are dispensed to patients by or through different types of medical providers, including but not limited to: (a) physicians who administer the drug in an office, (b) retail pharmacies, (c) home infusion pharmacies, and (d) other medical providers.

147. Providers regularly submit claims for reimbursement, seeking payment for the drugs from Medicare, insurers and patients. During the Class Period, the Defendants were aware that the Medicare program and virtually all end payors (the latter are included as members of the Class) use published AWPs to reimburse providers for drugs. Use of the published AWPs to establish reimbursement rates for drugs is an industry-wide practice and exists with respect to all classes of drugs, brand name and generic and is used for Part B drugs and non-Part B drugs.

148. There are several pharmaceutical industry compendia that periodically publish, in printed and electronic media, the AWPs for the tens of thousands of drugs on the market, including the *Drug Topics Red Book* (the "*Red Book*"), *American Druggist First Databank Annual Director of Pharmaceuticals* and *Essential Director of Pharmaceuticals* (the "*Blue Book*") and Medi-Span's *Master Drug Database* (collectively referred to herein as the "Publishers"). These Publishers publish AWPs for the various dosage forms for drugs. And the AWPs are published for Part B, non-Part B, brand name and generic drugs.

149. In periodically announcing the AWP for each drug, during the time period relevant to this Complaint the Publishers publish the prices that are supplied to them by the Defendant Drug Manufacturers for their respective drugs. For instance, the forward to the 1999 edition of the *Red Book* states that "all pricing information is supplied and verified by the products' manufacturers, and it should be noted that no independent review of those prices for accuracy is conducted." In addition, a June 1996 Dow Jones news article reported that Phil Southerd, an associate product manager of the *Red Book*, stated that it only publishes prices that

are faxed directly from the manufacturer. Thus, the Defendant Drug Manufacturers control the prices listed as the AWPs for each drug listed by the Publisher.

150. A system that bases its reimbursement rates for drugs on the published AWP is thus dependent on the honesty of the drug manufacturers. The Defendant Drug Manufacturers knew they could directly control and fabricate the AWP for their drugs at any time by forwarding to the Publishers a phony AWP. The Defendant Drug Manufacturers also knew that actual transaction price data – the amounts charged to providers and others for their drugs – was not publicly available, and they kept this information (on which AWPs should have been calculated) highly confidential and secret.

151. As detailed, the AWPs for the drugs at issue here bore little relationship to the drugs' pricing in the marketplace. They were simply fabricated and overstated in furtherance of Defendants' scheme to generate the profit spread to providers, PBMs and others and to increase Defendants' profits at the expense of Plaintiffs and the Class members.

152. Plaintiffs and the members of the Class paid for the drugs based on the inflated AWPs reported by the Defendant Drug Manufacturers.

153. The Defendant Drug Manufacturers' pattern of fraudulent conduct in artificially inflating the AWPs for their drugs (sometimes referred to herein as the "AWP Scheme") directly caused Plaintiffs and the members of the Class to substantially overpay for those drugs.

154. As detailed below, this overpayment manifested itself in two contexts, both of which were well known and understood by the Defendant Drug Manufacturers: (i) all drugs administered under Medicare Part B and (ii) drugs administered outside of the Medicare context whose reimbursement was established by use of AWP as a benchmark.

B. The Defendant Drug Manufacturers Commit AWP Fraud to Increase Market Share For Their Drugs Covered by Medicare Part B

1. The Medicare Insurance Program

155. In 1965, Congress enacted Title XVIII of the Social Security Act ("Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care.

156. The United States Department of Health & Human Services ("HHS") is responsible for the funding, administration and supervision of the Medicare Program. The Centers for Medicare and Medicaid Services ("CMMS"), formerly known as the Health Care Financing Administration ("HCFA"), is a division of HHS and is directly responsible for the administration of the Medicare Program.

157. The Medicare Program generally does not cover the cost of prescription drugs that a Medicare beneficiary self administers (*e.g.*, by swallowing the drug in liquid or pill form). However, Medicare Part B does cover some drugs, including injectables administered directly by a doctor, certain oral anti-cancer drugs, and drugs furnished under a durable medical equipment benefit. Approximately 450 drugs are covered by Medicare Part B.

158. In determining the amount it will pay, Medicare calculates the "allowed" amount for the drug. During the period 1992 through 1997, Medicare's reimbursement for Covered Drugs was set at the lesser of the estimated acquisition cost or national average wholesale price. For generic drugs (where more than one company sells a certain drug, sometimes called multiple-source drugs), payment was based on the lower of the estimated acquisition cost or the wholesale price that was defined as the median price for all sources of the generic form of the drug. This payment methodology was set forth in 42 C.F.R. § 405.517, a regulation first published in the Federal Register on November 25, 1991 and which became effective on or about January 1, 1992.

159. The estimated acquisition cost for a drug could be determined by the Medicare Program "based on surveys of the actual invoice prices paid for the drug" taking into

consideration the estimated acquisition cost, including "factors such as inventory, waste and spoilage." However, historically it has been the AWP published in the *Red Book* or other compendia that has been used as a ceiling for Medicare reimbursement.

160. On January 1, 1998, 42 C.F.R. § 405.517 was amended to provide that the allowed amount would be based upon the lower of the billed charge on the Medicare claim form or 95 percent of AWP.

161. The Medicare Program has publicly announced that it would use the AWP published in pharmaceutical industry magazines as the basis for reimbursement. Specifically, Program Memorandum AB-99-63 (dated September 1999 but re-issuing PM AB-98-76 dated in December 1998), a publicly available Medicare Program bulletin, confirmed that reimbursement for certain Medicare Part B drugs and biologicals "are paid based on the lower of the billed charge or 95 percent of the AWP as reflected in sources such as the *Red Book*, *Blue Book*, or Medi-Span."

162. Pursuant to PM AB-99-63, the AWP for a single-source drug or biological equals the AWP of the single product. For a multi-source drug or biological, the AWP is equal to the lesser of the median AWP of all of the generic forms of the drug or biological or the lowest brand name product AWP.

163. Medicare Part B reimburses medical providers 80% of the allowable amount for a drug. The remaining 20% is paid by the Medicare Part B beneficiary, and is called the "co-payment" amount. All medical providers are required by law to bill the 20% co-payment and make attempts beyond merely billing to collect that amount. In addition, beneficiaries under Part B are required to pay an annual deductible amount before Part B benefits are payable.

164. Some Medicare beneficiaries are able to purchase private Medigap insurance, which covers, among other things, all or part of the 20% co-payment for Covered Drugs.

165. In setting reimbursement rates, the Medicare Program uses the AWPs generated by the pharmaceutical industry. There are no regulations describing how AWPs are to be calculated, nor any regulatory process for approving them. Pharmaceutical companies do not report AWPs directly to the federal government, but instead send their pricing information to independent publishing companies that compile the data and publish the AWPs in trade publications, which are then used by the government, as well as private health plans.

166. The importance of an accurate AWP was recently reconfirmed by the Office of the Inspector General ("OIG") in an April 2003 report: "Compliance Program Guidance for Pharmaceutical Manufacturers." The OIG report found that the "government sets reimbursement with the expectation that the data provided are complete and accurate." The OIG report made it clear that the AWP must be a meaningful figure that is not artificially inflated:

> Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

167. And, the OIG rejected the notion that purposeful AWP manipulation was a lawful practice:

> The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit.

> Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.
>
> If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.
>
> In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. ***The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute***. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product. [Emphasis added.]

2. Congressional and Other Federal Investigations and Actions

168. The United States Department of Justice ("DOJ"), the United States General Accounting Office ("GAO"), the Office of the Inspector General at the United States Department of HHS ("OIG"), and certain Congressional subcommittees have been investigating the Defendant Drug Manufacturers and other pharmaceutical manufacturers for questionable practices regarding the industry's calculation of AWPs and for offering illegal incentives to providers.

169. In a letter dated September 28, 2000, sent from the House of Representatives Committee on Ways and Means, Subcommittee on Health to the President of the trade organization known as the Pharmaceutical Research and Manufacturers of America (most of the Defendant Drug Manufacturers are members of this association), Congressman Stark identified the improper scheme of manipulating AWPs and noted:

> This corruptive scheme is perverting financial integrity of the Medicare program and harming beneficiaries who are required to pay 20% of Medicare's current limited drug benefit.

170. In his September 28 letter, Congressman Stark made the following five "shocking conclusions":

> First – Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a de facto improper kickback for their customers.
>
> Second – Certain drug manufacturers have routinely acted with impunity in arranging improper financial inducements for their physicians and other healthcare provider customers.
>
> Third – Certain drug manufacturers engage in the fraudulent price manipulation for the express purpose of causing federally funded health care programs to expend scarce tax dollars in order to arrange de facto kickbacks for the drug manufacturers' customers at a cost of billions of dollars.
>
> Fourth – Certain drug manufacturers arrange kickbacks to improperly influence physicians' medical decisions and judgments notwithstanding the severely destructive effect upon the physician/patient relationship and the exercise of independent medical judgment.
>
> Fifth – Certain drug manufacturers engage in illegal price manipulation in order to increase utilization of their drugs beyond that which is necessary and appropriate based on the exercise of independent medical judgment not affected by improper financial incentives.

171. The DOJ and Congressional investigations are ongoing.

3. Certain of the Defendants Drug Manufacturers' Fraudulent Conduct Within the Medicare Part B Program

172. As set forth below, certain of the Defendants Drug Manufacturers each perpetrated the alleged fraudulent scheme by using some and/or all of the following practices:

a. Artificially Inflating AWPs

173. Each Defendant Drug Manufacturer provided AWPs for each of its drugs to the *Red Book*, the *Blue Book*, Medi-Span and other pharmaceutical compendia for Covered Drugs and non-Part B drugs, both brand name and generic.

174. During the Class Period, the Defendant Drug Manufacturers deliberately and intentionally published AWPs for Covered Drugs that did not reflect the actual pricing structure of the drugs, but was created solely to cause Plaintiffs and the Class members to overpay for the Covered Drugs. The Defendant Drug Manufacturers created and perpetuated this scheme so that the medical providers who purchased these drugs at a low cost would bill patients and their insurers at the inflated AWPs and earn a substantial profit from the "spread" between the real cost and the various AWP-related reimbursement rates.

175. The Defendant Drug Manufacturers knew and understood that Medicare and Plaintiffs and the Class members used the *Red Book* and other publications to determine the AWPs of the drugs. Because the Defendant Drug Manufacturers controlled the AWPs published in the *Red Book* and other compendia, the Defendant Drug Manufacturers knew and understood that they could manipulate the providers' profits from Plaintiffs and the Class. The purpose of artificially inflating the providers' profits was to create an illegal kickback to the providers, funded by Plaintiffs' and the Class members' overpayments.

176. As part of their scheme, the Defendant Drug Manufacturers specifically instructed and expected the providers to charge the inflated AWPs for Covered Drugs to Medicare, Plaintiffs and the Class members.

b. Improper Use of Free Samples

177. The Defendant Drug Manufacturers, through their sales personnel and marketing representatives, also provided free samples of their drugs to providers as a means of lowering the price. The free samples were used to offset the total cost associated with the purchases of the drugs, thereby increasing the "spread." Moreover, the Defendant Drug Manufacturers specifically told providers to bill Plaintiffs and the members of the Class for the free samples, which Defendants knew was unlawful.

178. Every free sample of a drug for which a provider bills a patient or insurer effectively reduces that provider's overall cost for that drug. However, the full cost of the Covered Drug was charged to the Plaintiffs and the Class members, and the free sample is not used by the drug company in calculating the AWP, which in turn inflates the AWP.

179. Although the Defendant Drug Manufacturers provided free samples and marketed them as a way to lower the providers' actual cost of the Covered Drugs, they did not include the value of the free samples in calculating the AWPs for those drugs. Thus, the Defendant Drug Manufacturers effectively and improperly passed on the cost of the free samples directly to Plaintiffs and the members of the Class.

c. Other Hidden and Improper Inducements and Price Reductions

180. The Defendant Drug Manufacturers also have provided and/or arranged for many other non-public financial inducements to stimulate sales of their Covered Drugs at the expense of Plaintiffs and the members of the Class. Such inducements included volume discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and educational and promotional grants. All of these incentives were designed to lower the providers' net cost of purchasing the Defendant Drug Manufacturers' Covered Drugs. And again, the value of these services was kept "off the book," so as to not be reflected in the AWP, which in turn inflates the AWP.

C. The Defendant Drug Manufacturers' Use of AWP Fraud to Increase and Maintain the Price of Drugs Outside of the Medicare Part B Context

181. The Defendant Drug Manufacturers' AWP fraud strikes well beyond Medicare Part B, adversely impacting health plans and their participants with respect to reimbursements for scores of other drugs. As described below, one such area is the use of AWPs by PBMs.

182. Health plans typically contract with intermediaries called pharmacy benefit managers ("PBMs") so that a health plan's participants can obtain brand name drugs from pharmacies or, via mail order, directly from the PBMs. In these contracts, the brand name drugs are priced at the AWP less a certain percentage "discount."

183. Pharmacy benefit managers – or "PBMs" – are fiscal intermediaries that specialize in the administration and management of prescription benefit programs. PBM clients include HMOs, employers, preferred provider organizations and other health insurers. Collectively, four PBMs comprise the significant market share of the PBM market. They are: AdvancePCS; Caremark; Express Scripts; and Medco Health. These four companies handle the drug benefits of 210 million people in the United States, or 70 percent of the nation's population.

184. For brand name drugs, PBMs use inflated "Average Wholesale Price" – or "AWP" – set by drug manufacturers as the basis for reimbursement (i) made by health plans to the PBMs for their members' drug purchases; and (ii) from the PBMs to the pharmacies for the purchases made by health plans' members. The PBMs typically contract with retail pharmacies to reimburse an amount equal to each drug's AWP, less a specified discount, plus a dispensing fee. Because the PBMs consider the contracting relationship with retail pharmacies to be confidential, health plans are never informed of the reimbursement amount to pharmacies. However, the PBM frequently pockets a "spread" or differential between charges paid to pharmacies and collected from clients. So, for example, clients may be charged the AWP minus 13 percent, but the retail pharmacy may only receive the AWP minus 15 percent, generating an undisclosed 2 percent spread for the PBM. Furthermore, as the example presented demonstrates,

PBMs are motivated to, and do place on their formulary those drugs with inflated AWPs: the greater the AWP inflation, the greater the profit to the PBM based on the 2 percent spread. A similar situation occurs for generic drug pricing based on Maximum Acquisition Cost ("MAC") lists, as the PBM uses one MAC list to charge clients and another MAC list to reimburse pharmacies. Further, with respect to mail order prescriptions, PBMs do business with companies that have the right to repackage drugs; they are called repackagers. These repackagers assign a new NDC number to a drug and publish a higher AWP. The PBM then negotiates with the repackager a discount off the AWP and tells the health plan it has saved a certain percentage off the AWP. But because the repackager's AWP is higher, the health plan pays more and the PBM pockets the spread between the AWP and the price paid to the repackager. PBMs also have mail order services in which case they act as the pharmacy. In this situation, the PBM keeps the spread between the AWP and the list price as there is no intermediary, like a pharmacy dispensing the drug. The PBMs keep this spread knowing that the AWPs are inflated and not the true AWP.

185. The Defendant Drug Manufacturers knew and understood that the PBM Defendants used the *Red Book* and other publications to determine the AWPs of the drugs. Because the drug manufacturers controlled the AWPs published in the *Red Book* and other compendia, the drug manufacturers knew and understood that they could help manipulate the PBMs' profits from Plaintiffs and the classes. The purpose of artificially inflating the PBMs' profits was to create an illegal kickback to the PBMs, funded by health plan and subscriber overpayments.

186. PBMs use the inflated AWPs set by drug manufacturers as the basis for the payments (i) made by health plans to the PBMs for their members' drug purchases, and (ii) from the PBMs to the pharmacies for the purchases made by health plans' members.

187. The PBMs typically contract with retail pharmacies to reimburse in an amount equal to each drug's AWP, less a specified discount, plus a dispensing fee. Because the PBMs consider the contracting relationship with retail pharmacies to be confidential, health plans are never informed of the reimbursement amount to pharmacies.

188. However, the PBMs frequently pockets a secret "spread" or differential between charges paid to pharmacies and collected from clients. So, for example, clients may be charged the AWP minus 13 percent, but the retail pharmacy may only receive the AWP minus 15 percent, generating an undisclosed 2 percent spread for the PBMs.

189. Furthermore, as the example presented demonstrates, PBMs are motivated to place on their formulary those drugs with inflated AWPs: the greater the AWP inflation, the greater the profit to the PBM based on the 2 percent spread.

190. A similar situation occurs for generic drug pricing based on MAC lists, as the PBM uses one MAC list to charge clients and another MAC list to reimburse pharmacies.

191. The PBMs deliberately utilize the inflated AWP to overcharge health plans for brand name drugs purchased by their participants and beneficiaries at retail pharmacies. An example of this practice was recently reported in the WALL STREET JOURNAL on March 30, 2003. According to the JOURNAL article, the AWP for fluoxetine is $2.66 a pill. With a 60 percent discount off the AWP, that brings the price to $1.06 a pill the PBM collects from the plan. Express Scripts pays the pharmacy 25 cents a pill and keeps the rest as profit. Express Scripts claims that currently its client pays 60 cents a pill, but since Express Scripts pays a pharmacy 25 cents per pill, it receives almost a 100 percent profit. And at the same time it was making this profit, Express Scripts was notifying its clients it was saving them money by having switched to fluoxetine, instead of Prozac.

D. The Defendant Drug Manufacturers' Use of AWP Fraud to Increase and Maintain Volume and Market Share For Generic and Multi-Source Drugs

192. The Defendant Drug Manufacturers' AWP fraud is most exacerbated for generic drugs or for brand name drugs for which there are biological or therapeutic equivalents.

193. Health plans and other sponsors of drug benefits contract with PBMs both so that the plan's participants can obtain ***brand name*** drugs from pharmacies or mail order distribution, but also so that they might receive ***multi-source***, or ***generic, drugs***. As with brand name drugs, reimbursement for multi-source, or generic, drugs is also related to a published average wholesale price for each generic drug manufactured and/or distributed by a generic drug company.

194. In the private payor arena, generic drug reimbursement is determined either in the same manner for brand name drugs (*i.e.*, a certain percentage "discount" off of the AWP), or is based on the amount specified as the maximum allowable cost or "MAC." MAC prices or reimbursements rates are a schedule of pricing for generically equivalent drugs based upon the listed average wholesale prices (AWPs) of competing generic drug manufacturers. The federal government originally introduced the concept of MAC reimbursement for generic medications. The CMS issues a MAC price list for generic products that have three or more manufacturers or distributors on the market. Because of this limitation, not all generics have a corresponding CMS MAC price.

195. PBMs often utilize this government-issued MAC reimbursement publication as a basis for their proprietary MAC list and supplement the list with other generic products or modify it for a variety of purposes. Sometimes, to stabilize the cost variance of different generic products of the same compound, pharmacy benefit administrators calculate a maximum allowable cost based on the list average wholesale prices of competing generic drug manufacturers (indeed, this is termed in the industry as the average average wholesale price or

"AAWP"). The resulting proprietary MAC generic drug reimbursement lists are typically based on the AAWP and, in turn, the AWP.

196. Accordingly, in the private payor arena generic drug reimbursement is closely tied to the published AWP for a generic drug. Generic drug makers are able to push market share for their generic drugs by intentionally increasing the published AWP for a generic drug with the intention to create a profit margin for others in the distribution chain. That profit margin is taken advantage of either directly (through reimbursement based upon the AWP for some plans and in some channels) or indirectly on the AWP based upon the establishment of a MAC tied to the AWP.

197. In the public payor arena under Medicare Part B, multi-source drugs or biologicals are also reimbursed on the basis of AWP. For multi-source drugs or biologicals, under Medicare Part B the AWP is equal to the lessor of the median AWP of all of the generic forms of the drug or biological, or the lowest brand name product AWP. Because reimbursement is pegged to the AWP, drug makers act in unison by elevating the AWP for all generic drugs, thereby inflating the amount of the reimbursement that occurs through Medicare Part B, including the Medicare co-payment through Part B.

198. As stated by one industry consultant:

> . . . This situation is more pronounced with generic drugs. Many generic companies have taken advantage of this use of AWP by substantially inflating their published AWPs.. . . [T]he system allows a retailer to acquire a drug at a low cost $2.50 per 100 tablets, for example) while relying on a published AWP ($20.00 or more) for its own pricing. It is not uncommon that the $25.00 retail price for a generic drug renders a gross profit well above $20.00 for the retailer. It is also common for the AWP of a generic product to remain stable while the actual selling price declines. . . .It is obvious that AWP is not an accurate measure of the prices manufactures charge. It must also be noted that not all generic products will be priced similarly. Some, in fact, use the more traditional method of a 20% markup to reach an AWP. This can be a handicap for generic companies choosing this method because retailers often use the AWP as the starting point for many pricing

decisions and an artificially high AWP provides the retailer with greater profits.

199. The raising of an individual Defendant's reported AWP for a multi-source drug raises the median AWP at which the generic drug is reimbursed. As a result, the publication and reporting of fraudulent AWPs by Defendants for generic drugs squarely fits generic drugs in which the cure of unlawful AWP inflation within the activity complained of in the MCC. Moreover, while any one generic manufacturer can only effect the median generic reimbursement AWP for a product, Defendants can and do create a spread between the median AWP and the actual prices paid by reporting AWPs that are far in excess of the actual wholesale prices while simultaneously maintaining or lowering actual wholesale prices.

200. Documents produced by Defendant generic manufacturers show that they are aware of the AWPs reported by their competitors and of the actual sales price of their generic competitors and that they manipulate their own AWPs in order to gain or maintain a competitive advantage in the market for their generic products. Each Defendant generic maker or distributor competes by inflating its AWP and thereby inflating the median AWP. The natural and expected result of this "leap frogging" of increasing AWPs is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP over 50,000% over actual costs. A few examples are set forth below:

Defendant	**Multisource Drug**	***RedBook* AWP**	**DOJ Determined Actual AWP**	**Percentage Spread**
Abbott	Sodium Chloride	$670.89	$3.22	20,735%
Baxter	Dextrose	$928.51	$2.25	41,167%
Baxter	Sodium Chloride	$928.51	$1.71	54,199%
BMS Group	Etoposide (Vepesid)	$136.49	$34.30	298%
Dey	Albuterol Sulfate	$30.25	$9.17	230%
Immunex	Leucovorin Calcium	$137.94	$14.58	846%
Pharmacia	Etoposide	$157.65	$9.47	1,565%
Sicor Group	Tobramycin Sulfate	$342.19	$6.98	4,802%
Watson	Vancomycin HCL	$70.00	$3.84	1,567%

201. In summary, generic or multi-source drugs are subject to fraudulent AWP manipulation as set forth in this Amended MCC.

202. The importance of AWPs to generic drugs was recently revealed in a lawsuit filed by Dey and two of the Publishers. In this lawsuit, Dey's allegations can be summarized as follows:

(a) Dey is a generic manufacturer, and generic manufacturers largely compete on price because they market products that contain the same active ingredients and are predominantly therapeutically interchangeable. (¶ 9 of Dey Complaint.)

(b) A large segment of the generic marketplace for respiratory drugs is comprised of a relatively small number of entities controlling purchase decisions. (¶ 12 of Dey Complaint.)

(c) The vast majority of prescription drug transactions – as much as 85% – are covered, in whole or in part, by third-party payor reimbursement arrangements such as managed care plans and Medicaid. (¶ 13 of Dey Complaint.) Both Medicaid and the private insurance system rely on reimbursement formulas that utilize the AWP. (¶¶ 14-16 of Dey Complaint.) ***This allegation confirms Plaintiffs' allegations in this Complaint that the AWP fraud impacts private markets, not just Medicaid***.

(d) Dey has an agreement with First DataBank and Medi-Span to provide the reporting services with AWP pricing information. Pursuant to this agreement (and in order to make Dey's products eligible for reimbursement through Medicaid Programs), Dey has reported WACs and AWPs. (¶¶ 26-32 of Dey Complaint.)

> In each case, until the events that have resulted in the present crisis, First DataBank has (except for some inadvertent errors) selected for listing in its published reports the AWP as suggested by Dey. For over ten years, until April 2003, no prices other than those submitted by Dey have been listed by First DataBank as AWP for Dey products in its databases [even though Dey also reported declining WACs for the products]."

(¶ 32 of Dey Complaint; *see also* ¶ 36 of Dey Complaint for similar allegation against Medi-Span.) This has also been the course of dealings between the Publishers and Dey's competitors:

> Virtually every drug manufacturer who participates in these reimbursement programs, and against whom Dey competes also communicates their suggested AWP prices to the reporting services. To the best of Dey's knowledge, with few, if any exceptions, First DataBank and Medi-Span have selected and reported the AWP pricing exactly as suggested by these competing manufacturers.

(¶ 37 of Dey Complaint.) *See also* ¶ 47 of Dey Complaint (recounting testimony of First DataBank representative who admits that First DataBank had always accepted the AWPs suggested by the manufacturers).

(e) Providers who dispense generic drugs "are cognizant of, and are highly attentive to, AWPs as reported by the recognized industry compendia published by First DataBank and Medi-Span because of the direct relationship between the level of reimbursement anticipated for the drugs selected and the reported AWPs of those drugs." (¶ 38 of Dey Complaint.) Indeed, Dey admits that it has relied on the publishers' practice of treating all manufacturers equally by simply reporting whatever AWP a manufacturer submitted. Consequently, First DataBank and Medi-Span have frustrated Dey's "reasonable expectations" by ***independently reporting*** an AWP different than that submitted by Dey. (¶ 39 of Dey Complaint.) These allegations become even more emphatic in a section of the Complaint titled "The Immediate Consequences of the Arbitrary Changes:"

> Since reimbursement to Dey's customers is, in Medicaid program in many states and in and [sic] insurance programs, most frequently based on the AWP as reported by the reporting services, this arbitrary and capricious reduction by First DataBank and Medi-Span in AWP would result in a drastic reduction in the reimbursement to drug providers who choose to dispense Dey's product. Since there has not been a comparable reduction in the AWP for Dey's competitors, there would be no comparable reduction in the reimbursement the purchasers of competitive products receive.

> Because reimbursement for Dey products would be significantly reduced, but reimbursement for those competing products would remain as they have been, Dey is prevented, by First DataBank's and Medi-Span's arbitrary and capricious acts, from effectively competing in the marketplace.
>
> In fact, within one day of learning that First DataBank and Medi-Span had arbitrarily changed Dey's AWP, Dey has already been contacted by at least nine of its customers complaining about the drastic changes and indicating that, because of those changes, the customers would not be able to purchase Dey products since they could not earn a reasonable profit from the sale of such products.
>
> Further, at least one customer has already indicated that he had canceled all of his purchases presently on order from Dey and was, instead, buying those products from Dey's direct competitors.
>
> ….. These providers will cease to purchase and dispense Dey's drugs if the reimbursement for those drugs is a fraction of those obtained from competing companies. Because purchasing decisions are highly concentrated in this industry among wholesalers and group purchasing organizations, this scenario is playing out across the country and threatens to eliminate sales of Dey's products that are covered by Medicaid and insurance reimbursement programs.

(¶¶ 50-54 of Dey Complaint.)

203. ***These allegations confirm the allegations herein that medical providers rely on spreads in dispensing (and, consequently, so do the manufacturers in order to move market share).*** Further, these allegations are akin to saying: "We all committed fraud on an even basis, but now only my competitors can commit fraud; consequently, I have now suffered damage."

E. Defendants' Concealment of the Truth

204. Each Defendant concealed its fraudulent conduct from the Plaintiffs and the Class by controlling the process by which the AWPs for Covered Drugs and brand name drugs were set. Defendants prevented Plaintiffs and the Class Members from knowing what the actual pricing structures for these drugs were, and failed to inform them of the usage of free samples and the provision of other financial incentives to providers and other intermediaries to lower their respective costs for the drugs. Moreover, Defendants' fraudulent conduct was of such a nature as to be self-concealing.

205. Each Defendant closely guarded its pricing structures and sales figures for their Covered Drugs and brand name drugs. CMS Health Care Industry Market Update (dated January 10, 2003) stated that drug "price discounts are closely guarded as competitive information." *See* p. 39.

206. Each Defendant also concealed its fraudulent conduct by instructing providers and others not to report the prices they paid for the Covered Drugs and brand name drugs, respectively.

207. Each Defendant also worked with and motivated provider and intermediary trade associations to halt any investigations or change in the AWP system.

208. Each Defendant's efforts to conceal its pricing structures for Covered Drugs and brand name drugs is evidence that it knew that its conduct was fraudulent.

209. Thus, each Defendant concealed that (i) its AWPs were highly-inflated (and were inflated solely to cause Plaintiffs and the Class to overpay for the AWPIDs), (ii) it was manipulating the AWPs of the AWPIDs, and (iii) the AWPs bore no relationship to the prices paid for, or the pricing structure of, the AWPIDs as they were sold to providers and others.

210. Plaintiffs were diligent in pursuing an investigation of the claims asserted in this Complaint. Through no fault of their own, they did not receive inquiry notice nor learn of the factual basis for their claims in this Complaint and the injuries suffered therefrom until recently.

F. Tolling of Applicable Statutes of Limitation

211. Any applicable statutes of limitations have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiffs and members of the Class have been kept in ignorance of vital information essential to knowledge of and the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiffs and members of the Class could not reasonably have discovered the fraudulent nature of the published AWPs.

212. Defendants were and continue to be under a continuing duty to disclose to Plaintiffs and the Class the fact that the published AWPs bore and continue to bear no relationship to the prices or pricing structures for Covered Drugs and brand name drugs. Because of their knowing, affirmative, and/or active concealment of the fraudulent nature of the published AWPs, Defendants are estopped from relying on any statutes of limitations.

V. EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT

213. Due to acts of concealment by each Defendant, the following examples of the specific unlawful conduct engaged in by each particular Defendant are merely illustrative. They are not intended to be an exhaustive account of all of the unlawful activity engaged in by each Defendant. Instead, these allegations allege the circumstances of the wrongdoing with some detail. Additional detail is peculiarly within the Defendants' control and warrants that further discovery should proceed as to each drug identified in this Complaint as well as other drugs whose AWP is published by any Defendant.

A. Abbott

214. Abbott engages in an organization-wide and deliberate scheme to inflate AWPs. Abbott has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Abbott for which relief is currently sought in this case are set forth in Appendix A or in the proposed class certification order, and are summarized below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
ABBOTT	A-Methapred	methylprednisolone sodium succinate	Anti-Inflammatory Agent Used to provide relief for inflamed areas of the body. Also used for control of allergic processes
	Aminosyn	amino acid	Nitrogen Product Used as a nutritional supplement
	Biaxin	clarithromycin	Macrolide (Anti-Infective Agent) Used to treat mild to moderate infections
	Calcijex	calcitrol	Hormone Used in the treatment of hypocalcemia

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Depakote	divalproex sodium	Anticonvulsant Used in the treatment of complex partial seizures
	Ery-tab	erythromycin, enteric-coated	Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various infections
	Erythromycin	erythromycin base	Antiacne Agent; Anti-Infective Agent Used in the treatment of various infections
	Liposyn II	fat emulsion	Caloric Agent; Nutritional Supplement Used as a nutritional supplement
	Prevacid	lansoprazole	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of duodenal ulcer and erosive esophagitis
		acetylcysteine	Mucolytic (Respiratory Agent: Diagnostic Aid) Used for certain lung conditions when increased amounts of mucus make breathing difficult
		acyclovir sodium	Anti-Infective Agent Used in the treatment of herpes infections
		amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
		cimetidine hydrochloride	Gastrointestinal Agent Used in the treatment of duodenal ulcer and prevention of ulcer recurrence
		clindamycin phosphate	Anti-Infective Agent Used in the treatment of vaginal infections
		dextrose	Caloric Agent Used to increase intake of calories and fluids
		dextrose sodium chloride	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
		diazepam	Central Nervous System Agent Used to treat status eplipeticus and anxiety disorders. Also used as an amnesic prior to surgical procedures
		fentanyl citrate	Central Nervous System Agent Used for anesthetic purposes
		furosemide	Diuretic Used in the treatment of edema associated with cirrhosis and kidney disease. Also used to manage hypertension

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		gentamicin sulfate	Anti-Infective Agent Used as a general antibiotic to treat serious gastrointestinal, respiratory, bone, skin and soft tissue infections
		heparin sodium or heparin lock flush	Blood Modifier Used to prevent and treat thrombosis and pulmonary embolism. Also used as an anticoagulant in blood transfusions and dialysis procedures
		leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
		lorazepam	Central Nervous System Agent Used in the treatment of anxiety disorders
		sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion
		tobramycin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat severe infection
		vancomycin hydrochloride	Antibiotic Agent (Anti-Infective Agent) Used as a general antibiotic

1. Abbott Has Been The Target of Government Investigations

215. In connection with its scheme to inflate AWPs, Abbott has been investigated by the United States Department of Justice, Commonwealth of Massachusetts, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, the Attorney General for the State of California, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse.

216. These investigations confirm that Abbott has engaged in a deliberate scheme to inflate the published AWPs for many of its drugs. According to Representative Pete Stark, the ranking member of the Congressional Ways and Means Committee:

> The price manipulation scheme is executed through Abbott's inflated representations of average wholesale price ("AWP") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP and DP versus the true price providers are paying, is

> regularly referred to . . . as "the spread." The evidence . . . clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Abbott manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs. This was achieved by arranging financial benefits or inducements that influenced the decisions of health care providers submitting Medicare and Medicaid claims.

See October 31, 2000 letter from U.S. Representative Pete Stark to Miles White, Chief Executive Officer of Abbott. (P007647-78.)

2. Abbott Controls the Published AWP for Its Products

217. Abbott has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

3. Abbott's AWP Manipulation Benefited Providers at the Expense of the Class

218. The purpose of Abbott's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

a. For example, Abbott anticipated that the spread between AWP and cost would be eliminated by legislative changes in 1997. Accordingly, Abbott looked for ways to maximize the profit spread immediately. In one internal memorandum about a third party's pricing product, Abbott states:

> One of GeriMed's goals of obtaining maximum profitability for its members presents an opportunity for our injectables. They think there is about an 18 month window of opportunity to promote our injectables as more profitable for their members to use because of the bigger spread between AWP and cost. Legislative changes in reimbursement are expected to do away with this spread advantage by mid 1997.

(ABT AWP/MDL 015839) (Highly Confidential).

b. In a second memorandum about this same product, Abbott states:

> The purpose of these programs was to "enhance revenue and decrease cost." *** These suggestions are made to save money through lower contract pricing or increase revenue through better spread between AWP and contract price.… The [distributor's] program identifies the lowest cost product and ***the best spread for the particular state***.

(ABT AWP/MDL 010407-09) (Highly Confidential) (emphasis added).

219. Abbott tried to maximize spread because it understood that its customers routinely engaged in "spread shopping" – comparing Abbott's AWPs with those of its competitors in order to determine the greatest spread (and therefore sell or administer the drug with the greatest spread). An example is a document produced by Abbott, prepared by a customer in late 1993, comparing Abbott's proposed contract price and its published AWPs with that of Baxter's competing generic drugs. (ABT AWP/MDL 028546) (Highly Confidential).

220. Just as Abbott motivates providers to administer drugs based on the AWP, Abbott's 1996 Pricing Guidelines reveal that Abbott rewards PBMs based on the degree of influence they exert to drive utilization of Abbott products. (ABT AWP/MDL 053922-23) (Highly Confidential).

4. Specific Abbott AWPs Documented by the DOJ

221. In a report published by the DHHS (the "DHHS Report"; PM Rev. AB-00-86, "An Additional Source of Average Wholesale Price Data In Pricing Drugs and Biologicals Covered by the Medicare Program," Sept. 8, 2000), the DOJ documented at least 81 instances where the published AWPs for various dosages of 16 drugs manufactured by Abbott were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 16 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Abbott in the 2001 *Red Book*.

Drug	Abbott's 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Acetylcysteine	$35.87	$21.90	$13.97	64%
Acyclovir	$1047.38	$349.05	$698.33	200%
Amikacin Sulfate	$995.84	$125.00	$870.84	697%
Calcitriol (Calcijex)	$1,390.66	$1079.00	$311.66	29%
Cimetidine Hydrochloride	$214.34	$35.00	$179.34	512%
Clindamycin Phosphate	$340.52	$75.35	$265.17	352%
Dextrose	$239.97	$3.91	$236.06	6,037%
Dextrose Sodium Chloride	$304.38	$1.93	$302.45	15,671%
Diazepam	$28.50	$2.03	$26.47	1,304%
Furosemide	$74.52	$14.38	$60.14	418%
Gentamicin Sulfate	$64.42	$.51	$63.91	12,531%
Heparin Lock Flush	$38.30	$13.60	$24.70	182%
Metholprednisolone Sodium Succinate	$34.08	$2.30	$31.78	1,382%
Sodium Chloride	$670.89	$3.22	$667.67	20,735%
Tobramycin Sulfate	$150.52	$2.94	$147.58	5,020%
Vancomycin Hydrochloride	$382.14	$4.98	$377.16	7,574%

(P006299-316.)

5. Additional Evidence Concerning Vancomycin

222. At least one Publisher, Medi-Span, challenged the manner in which Abbott set its AWPs for vancomycin. The following statement appeared in a February 9, 1996 faxed letter to Abbott from a representative of Medi-Span:

> It appears that the only difference between these two products listed is the vial it comes in. If it is, please let us know why the $400 plus difference in AWPs?... [T]his customer claims he can get Vancomycin for $6 or $7 per vial DP as opposed to the $52.94 and $19.50 the Abbott Vancomycin cost.

(ABT AWP/MDL 001215.)

223. The government investigation into Abbott's AWP for vancomycin identified:

> prices that are routinely made available to many providers, but are far below Medicare reimbursement rates. They include 1999 prices for vancomycin, the Abbott Labs-manufactured antibiotic, which a health care provider could buy for $76.00 but for which the AWP upon which Medicare's reimbursement was based on was $261.84.

See September 25, 2000 letter from U.S. Rep. Tom Bliley to the Honorable Nancy-Ann Min DeParle, Administrator of the Health Care Financing Administration. (P007015-490.)

224. For other doses of vancomycin, Abbott reported an AWP of $68.77 as of April 2000. The DOJ adjusted it to $8.14.

6. Additional Evidence for Amikacin

225. One published report states: "Amikacin, used to treat an infection that HIV+ people get and manufactured by Abbott, had an AWP of $54.56. DOJ said the actual price was $6.75." *See States Mull Suit Against Drug Companies*, www.stateline.org (April 2, 2001) (P011268-70).

7. Inflated AWPs From Abbott Price Lists

226. In response to government subpoenas, Abbott produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Abbott has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1 and 2 are a number of those drugs (not already referenced above) with spreads in excess of 100% from two specific Abbott customers.

227. Table 1 is an analysis of certain dosages of Abbott drugs from a document entitled "2000 Manufacturer Listing of Pharmaceutical Awards – GeriMed." (ABT AWP/MDL 031024-62) (Highly Confidential).

Table 1

Drug	Contract Price	AWP	$ Diff AWP	% Spread
alcohol injection	30.30	78.98	48.68	160.66
aminosyn (amino acid)	36.48	125.10	88.62	242.93
aminocaproic acid	17.75	41.88	24.13	135.94

Drug	Contract Price	AWP	$ Diff AWP	% Spread
amphotericin b	4.65	10.94	6.29	135.27
atacurium besylate	104.80	217.75	112.95	107.78
bleomycin sulfate inj	95.00	305.78	210.78	221.87
bretylium tosylate	215.52	567.60	352.08	163.36
Marcaine (bupivacaine hcl)	13.40	32.01	18.61	138.88
AbboCath (catheter iv)	113.00	540.00	427.00	377.88
Chromium TR Meta (chromic chloride)	12.00	30.00	18.00	150.00
Copper Trace (cupric chloride)	12.00	30.00	18.00	150.00
Dopamine	17.00	34.88	17.88	105.18
Doxorubicin hcl inj	62.50	151.25	88.75	142.00
Epinephrine	7.00	15.94	8.94	127.71
halothane inhalation anesthetic	269.94	708.75	438.81	162.56
irrigation set peritoneal dialysis	103.80	245.00	141.20	136.03
ketorolac tromethamine	29.50	87.38	57.88	196.20
lidocaine hcl inj	77.04	216.90	139.86	181.54
mangenese chloride	10.50	30.00	19.50	185.71
Mannitol	21.50	50.53	29.13	135.49
Carbocaine (mepivicaine)	4.67	11.34	6.67	142.83
metoclopramide inj	27.25	98.75	71.50	262.39
nalbuphine inj	5.10	11.38	6.28	123.14
Neostigmine methylsul inj	10.40	42.50	32.10	308.65
pancuronium bromide	32.63	170.94	138.31	423.87
Pentamidine isethionate inj	19.00	91.84	72.84	383.37
potassium acetate	11.50	40.00	28.50	247.83
Novocaine (procaine inj)	37.25	84.95	47.70	128.05
sodium acetate inj	12.00	42.50	30.50	254.17
vincristine inj	3.00	36.14	33.14	1104.67
water for injection bacteriostatic	6.50	13.44	6.94	106.77
zinc chloride inj	11.75	30.00	18.25	155.32

228. Table 2 is an analysis of a certain dosage of Abbott's drug Toposar from a document entitled "2000 Manufacturer Listing of Pharmaceutical Awards – IVMed." (ABT AWP/MDL 031000-23) (Highly Confidential).

Table 2

Drug	Contract Price	AWP	$ Diff AWP	% Spread
Toposar (etoposide inj)	26.32	286.63	260.31	989.01

229. As set forth above, Abbott's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

B. Amgen

1. The Drugs at Issue and Their Competitive Environment

230. Amgen engages in an organization-wide and deliberate scheme to inflate AWPs. Amgen has stated fraudulent AWPs for all or almost all of its drugs, including: Epogen (eportin alfa for ESRD use),[1] Neupogen (filgrastim), Aranesp (darbepoetin alfa), Enbrel (etanercept), Kineret (anakrina), and Neulasta (pegfilgrastim). The specific drugs of Amgen for which relief is sought in this case are set forth in Appendix A and are set forth below and the complaint includes all NDCs for these drugs:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
AMGEN	Aranesp	darbepoetin alfa albumi	Antianemic Agent; Blood Modifier Used in the treatment of anemia associated with chronic renal failure and/or chemotherapy
	Enbrel	etanercept	Antirheumatic Agent Used to reduce signs and symptoms of rheumatoid arthritis
	Epogen	epoetin alfa	Antianemic Agent; Blood Modifier Used in the treatment of anemia associated with chronic renal failure, chemotherapy and/or HIV-infected patients
	Kineret	anakrina	Antirheumatic Agent Used in the treatment of moderate to severe rheumatoid arthiritis

[1] In the Medicare Part B context, reimbursement for Epogen is not based on the AWP, but rather on a specific dollar amount set by statute. However non-Medicare Part B reimbursement for Epogen is based on AWP for many Class members.

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Neulasta	pegfilgrastim	Antineoplastic; Blood Modifier Used to decrease incidence of infection (neutropenia) in some cancer patients
	Neupogen	filgrastim	Antineoplastic; Blood Modifier Used to decrease incidence of infection (neutropenia) in some cancer and leukemia patients

224A. Amgen introduced EPOGEN® (Epoeitin alfa) in 1989. EPOGEN® is indicated for the treatment of anemia in patients with chronic renal failure on dialysis. In 2001, Aranesp® (darbepoetin alfa), an erythropoietic protein with greater biological activity and a longer half-life than Epoetin alfa, was approved for the treatment of anemia in patients with chronic renal insufficiency. In 2002, Aranesp® was also approved for the treatment of chemotherapy-induced anemia. By 2003 Aranesp had sales of $283 million.

224B. NEUPOGEN® (filgrastim) was approved in 1991. NEUPOGEN® is indicated for decreasing the incidence of infection associated with chemotherapy-induced neutropenia in cancer patients with nonmyeloid malignancies. In 2002, Amgen introduced Neulasta® (pegfilgrastim), a longer-acting form of filgrastim approved for the same use but requiring only one injection per chemotherapy cycle.

231. Since its introduction, Aranesp has been locked into a knock-down competitive battle with Ortho Biotech's Procrit.

225A. A review of their respective websites reveals that Amgen and Ortho are targeting the exact same type of patient with respect to use of Aranesp and Procrit. Amgen describes Aranesp on its website as follows:

> That's where Aranesp® can help. Aranesp® stimulates natural production of red blood cells boosting the number of red blood cells in the body, which can increase the amount of oxygen in your blood and give you more energy. And since you will need fewer shots and doctor visits, you can begin to feel less like a patient and more like a person – and get back to being you again.

> Aranesp® is available by prescription only. Aranesp® has been approved by the Food and Drug Administration to treat the anemia associated with chronic renal failure (renal disease) in people with reduced kidney function or on dialysis. People who have uncontrolled high blood pressure should not use Aranesp®.

225B. Ortho promotes and describes Procrit on its website as follows:

> PROCRIT® (Epoetin alfa) is for the treatment of anemia in patients who have chronic kidney disease and are on dialysis. PROCRIT has a proven safety record. Your doctor should carefully monitor your blood pressure and hemoglobin for rapid increases, which should be avoided. PROCRIT is available by prescription only and is administered by your health care provider.

(Emphasis added).

232. Thus, these two companies were targeting the exact same patients and have an incentive to compete based on the spread that they could offer physicians.

226A. Amgen's Neupogen also competed with Immunex's Leukine prior to Amgen's acquisition of Immunex. Both of these drugs are Part B covered drugs and as set forth below this competitive landscape became a breeding ground for competition based on spread or discounts off AWP. Competition also existed between Amgen's Remicade and Immunex's Embrel, which created a climate for using the spread between AWP and acquisition cost as an inducement to wholesalers and other providers.

2. Amgen's Definition and Understanding of AWP

226B. Internally, Amgen defines AWP as "the common basis for reimbursement by payors. AWP may not necessarily reflect the actual purchase price" (Press Release, "Data from Study Shows Aranesp …," Dec. 9, 2002 (www.amgen.com)) or "one of the factors used by Medicare to determine payment for drug charges."

3. Amgen Controls the Published AWP for Its Products

233. Amgen has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

4. Amgen Understands the Importance of Reimbursement Rates

227A. Amgen was well aware that its customers' profits depended on reimbursement rates for drugs, and that Amgen's own sales and profits in turn depended on its customers' reimbursement payments and profits:

> Our sales depend on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement rate could result in decreased sales of our products.
>
> In both domestic and foreign markets, sales of our products are dependent, in part, on the availability of reimbursement from third-party payors … ***we believe that sales of Aranesp and Neulasta are and will be affected by government and private payor reimbursement policies***. … If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will administer them, which could reduce the use of our products or cause us to reduce the price of our products. This could result in lower product sales or revenues …

(Amgen 2002 Form 10-K at 43-44).

227B. The foregoing references referring to "reimbursement policies" refers to policies that use AWP as the benchmark for reimbursement.

234. Amgen also made sure its sales representatives were focused on reimbursement and customer profit motives. A senior Amgen sales manager has publicly stated:

> Reps need to understand the insurance system flawlessly. They need to understand the money trail in terms of how a drug gets reimbursed, who reimburses it, and coverage or policy limitations – those are fundamental questions."

228A. Part of that "understanding" was an explanation by Amgen sales representatives that was routinely made by sales representatives to physicians concerning profit that a physician could make by purchasing at a discount off AWP. With respect to, for example, Aranesp and Neupogen, Amgen sales representatives either handed out calculations showing the spread off of AWP that a provider could realize by using Amgen's drugs, or orally reviewed such profits with physicians.

228B. Amgen has also established a website (www.reimbursementconnection.com) to help providers with reimbursement issues, including information on how to calculate reimbursement for Amgen drugs and Sample Reimbursement Sheets detailing how much Medicare will pay for Amgen drugs. In addition, Amgen maintains a telephone Reimbursement Hotline for providers or their office staffs to call to get help with reimbursement questions.

235. Amgen actually promotes the use of AWPs for reimbursement purposes on its website as follows:

Sample of Reimbursement Payments for Aranesp® Syringe/Vial Strengths

		Medicare		
Syringe/Vial Strength	**Average Wholesale Price (AWP)[1/2]**	**85% of Medicare Allowable (AWP)**	**Payment[1] (at 80%)**	**Secondary Insurer or Patient Co-Payment[2] (at 20%)**
J0880 – 25 mcg*	$124.69	$105.99	$84.79	$21.20
J0880 – 40 mcg*	$199.50	$169.58	$135.66	$33.92
J0880 – 60 mcg*	$299.25	$254.36	$203.49	$50.87
J0880 – 100 mcg*	$498.75	$423.94	$339.15	$84.79
J0880 – 150 mcg**	$748.13	$635.91	$508.73	$127.18
J0880 – 200 mcg*	$997.50	$847.88	$678.30	$169.58
J0880 – 300 mcg*	$1,496.25	$1,271.81	$1,017.45	$254.36
J0880 – 500 mcg†	$2,493.80	$2,119.73	$1,695.78	$423.95

[1]As reported in *Drug Topics Red Book®*, February 2004.
[2] Most private insurers base reimbursements for drugs on a percentage above or below published AWP.
* These strengths are available in either Arenesp® SingleJect® prefilled syringes or vials.
† Available only in Aranesp® SingleJect® prefilled syringe.
** These strengths are available in vials only.

229A. In the above table, Amgen recognizes the impact of an AWP-based price on a "secondary insurer" or patient making copay. Amgen thus promotes AWP all the while knowing that the posted AWP is artificially inflated as described.

5. Specific Examples of AWP Abuse

229B. At all relevant times Amgen understood that reimbursement for its drugs was dependent upon AWP. Amgen set the AWPs for its products in an arbitrary manner that rendered AWP to be a fictitious number in that it failed to account for rebates, volume discounts and other incentives provided to physicians and others purchasing Amgen drugs.

236. Both Procrit and Aranesp are Part B covered drugs, hence given the competition between the two, one clear way to increase market share was to increase the spread and hence the profit to providers. Indeed at Aranesp's launch to the oncology market Amgen sales representatives had ready at their fingertips information concerning Aranesp's AWP, the Medicare reimbursement amount, WAC, WAC minus discounts and the "profit" created by the spread between Medicare reimbursement and net acquisition cost.

230A. It was intended by Amgen's top sales executives that its sales force would use this "profit" as a basis for marketing Aranesp.

230B. Examples of the improper use of AWPs by Amgen are set forth below. For example, to increase its market share Amgen in 2003 offered Aranesp to customers with a rebate or discount of up to 30% off of list price, which in itself is 20%-25% off of the published AWP. Thus, Amgen was offering spreads of 50% or more off of the published AWP on Aranesp. These spreads are being offered while Amgen is promoting use of AWP on its own website.

237. On or about July 18, 2003, Amgen extended this discount through July 15, 2004. Thus, even in the face of this litigation, Amgen was offering substantial discounts which rendered the reported AWPs inflated and without basis.

231A. The spread on Aranesp was created at the time of its introduction, and Amgen has published an AWP that created at times at least a 40% spread between the estimated cost to a dispenser and AWP. Given the significant cost of Aranesp this is about $300 per unit for most NDCs. If a typical treatment involves two doses twice a month for a three- to four–month

period, the cost of this spread is $1800 - $2400 per patient. For a Medicare patient this could increase co-payments by $360 - $480.

231B. The use of rebates and off-invoice discounts did not start in 2003 but occurred shortly after Aranesp was introduced in 2002. The allegation is based on (a) the fact that the competition between Amgen and Ortho existed before 2003, (b) that Ortho was heavily engaged in its own conduct directed at marketing the spread and Amgen needed to respond in kind, (c) Amgen was offering "introductory" discounts that inflated AWP, and (d) as noted above Amgen sales representatives were armed with calculations showing the profit created by the Aranesp spread. Ortho, at national sales meetings, authorized its sales and marketing representatives to provide free samples as a means of lowering acquisition costs to providers. Ortho also used inducements such as educational and promotional grants to win over clinics and other providers and as credit memos which were inducements for a clinic or provider to use Procrit exclusively. Amgen sales representatives learned of these efforts and reacted to them by offering inducements of their own. These inducements included rebates based upon volume used by the practitioner.

238. Amgen's efforts at using inflated AWPs to increase market share were successful as Aranesp sales have steadily increased.

232A. Amgen's AWP-related manipulation did not stop at Aranesp. Prior to its acquisition of Immunex, Amgen competed with Immunex with respect to its drug Neupogen and Immunex's Leukine. Documents produced by Immunex reveal that Immunex was marketing Leukine based on the spread, promoting its spread of $80.60 per vial as an advantage over Amgen's $51.61 spread per vial. At the time of this spread marketing by Immunex, Amgen published an AWP for Neupogen of roughly $263.30, and was selling its product to doctors at $201.16. This created a spread of 31% off of AWP which, given the high price of each vial,

would have a substantial impact on co-payors and third-party payors, and provided a handsome profit to providers.

232B. Amgen's use of the spread did not go unnoticed by competitors. In an internal memorandum, employees of a competitor, Centecor, wrote in the context of "reimbursement issues" that doctors have a "fear of audit and not being perceived as infusing only for profit," *i.e.*, using infusion where other treatments were available, but noted that Amgen had no issues in encouraging oncologists to choose drugs based on the spread:

> We need to do a stronger job up front driving home the patient benefit of PMP. One of the other reasons I see doctors hitting a point and not moving forward is fear of audit and not being perceived locally as infusing only for profit. An example of what goes on in other specialties might be of benefit – personally I would use an ***Amgen*** or Immunex oncology product and show the AWP versus payment. ***As you know these companies have been telling Rheums it is unethical to receive payment for prescribing an agent but have no problem promoting this concept to oncologists.*** We don't need to make this a big production–if you put the slide up with the product and company the attendees can connect the dots.

239. The foregoing e-mail is in effect competitor intelligence confirming that Amgen was marketing the spread on its products sold to oncologists, which include Aranesp, Neulasta and Neupogen.

233A. Spreads created for Neupogen are set forth below for a 300ml dose. Not only are the spreads sizable, but reported AWPs increased faster than the real AWP, thus making the reported AWPs in later years even more inflated. This increase in spread is the direct result of an effort to induce physicians to use Neupogen due to the increase in the spread:

Year	Reported AWP	Real AWP	Spread in Dollars	Percentage
1997	$161.30	$125.09	$36.21	28
1998	$165.30	$130.02	$35.28	27
1999	$180.40	$134.81	$45.91	34
2000	$188.50	$140.49	$39.88	28
2001	$197.80	$148.62	$49.18	33
2002	$207.50	$149.60	$57.90	38

233B. Spreads for the 10,000 u/ml ten pack for Epogen were historically approximately 33%, but beginning in January 2000 Amgen implemented a series of AWP increases so that by 2002 the spread increased to 42%. The increase in spread was designed to increase market share.

240. AWPs for the 4,000 units/ml of Epogen were also inflated with spreads between 92% and 105%. AWPs for this drug/dose increased while costs to the provider decreased. Similarly, the ten pack 4,000 units/ml dose started in 1997 with a spread of 26% that increased to 47% over time.

234A. Amgen has also caused artificially inflated AWPs to be published for its top-selling drug Enbrel. Originally, the spread between AWP and acquisition cost was 25%. This spread has steadily increased over time such that for some doses, the spread is 32% to 40%. Amgen has created this spread to encourage promotion and use of Enbrel by those in the distribution chain.

6. Amgen Rebates on Epogen

2334B. In addition to marketing the spread, Amgen has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price.

241. A 1993 OIG Report detailed how Amgen gave substantial year-end rebates to its customers based on their purchases of Epogen. The report noted that Medicare and Medicare beneficiaries did not receive the benefit of any rebates; all monies remained with the provider. There was no way to provide for any rebates on Medicare claim forms, and Amgen's rebates were not provided until year-end:

> [T]he effect of the rebates is that it reduces the actual cost of EPO to a dialysis facility, thus increasing their gross profit. Presently, the rebates represent price reductions which benefit the facilities exclusively.

("Review of Epogen Reimbursement," (OIG A-01-02-00506 at 7-8)).

235A. By utilizing hidden inducements, Amgen provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

242. Amgen's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of hidden rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

7. Amgen Concealed Its AWP Manipulation

236A. Amgen deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, as noted above, Amgen gave rebates to its Epogen customers which effectively lowered the true price charged. When OIG asked Amgen for data on its total sales or the total amount of Epogen rebates, Amgen refused to provide such data. ("Review of Epogen Reimbursement," (OIG A-01-02-00506 at 7-8)).

243. In September 2001, the GAO reported that epoetin alfa accounted for the second highest percentage of Medicare expenditures on drugs in 1999, accounting for 9.5% of spending for prescription drugs by Medicare in 1999 and for 3.4% of all Medicare allowed services.

237A. As set forth above, Amgen's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

C. AstraZeneca

244. AstraZeneca has engaged in an ongoing deliberate scheme to inflate AWPs. The drugs at issue for this defendant are identified in Appendix A and summarized below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
ASTRAZENECA	Accolate	zafirlukast	Leukotriene Antagonist (Respiratory Agent) Used in the treatment of asthma
	Armidex	anastrozole	Antiestrogen (Antineoplastic: Hormonal Agonist/Antagonist) Used in the treatment of breast cancer in postmenopausal women

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Atacand	candesartan cilexetil	Angiotension II Receptor Antagonist (Cardiovascular Agent) Used in the treatment of hypertension
	Atacand HCT	candesartan cilexetil-hydrocholorothiazide	Angiotension II Receptor Antagonist With Diuretic (Cardiovascular Agent) Used in the treatment of hypertension
	Casodex	bicalutamide	Antineoplastic Used in the treatment of prostate cancer
	Diprivan	propofol	General Anesthetic Used in the induction or maintenance of anesthesia as part of balanced anesthetic technique
	Entocort	budesonide	Glucocorticoid Used in the treatment of Crohn's disease
	Nexium	esomeprazole magnesium	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of heartburn and erosive esophagitis
	Nolvadex	tamoxifen citrate	Antiestrogen (Antineoplastic: Hormonal Agonist/Antagonist) Used in the treatment or prevention of breast cancer
	Prilosec	omeprazole	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of gastric and duodenal ulcers, gastroesophageal reflux disease and erosive esophagitis
	Pulmicort	budesonide (inh)	Glucocorticoid Used for maintenance treatment of asthma
	Rhinocort	budesonide (nasal)	Glucocorticoid Used in the treatment of allergic rhinitis
	Seroquel	quetiapine fumarate	Antipsychotic Agent (Psychotherapeutic Agent) Used in the treatment of schizophrenia
	Toprol	metoprolol succinate	Beta Adrenergic Blocking Agent (Cardiovascular Agent) Used in the treatment of hypertension, angina pectoris and heart failure
	Zestril	lisinopril	Angiotension Converting Enzyme Inhibitor (Cardiovascular Agent) Used in the treatment of hypertension and heart failure

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Zoladex	goserelin acetate	Gonadotropin Releasing Hormone Analogue (Antineoplastic: Hormonal Agonist/Antagonist) Used in the treatment of prostate and advanced breast cancer
	Zomig	zolmitriptan	Serotonin Receptor Agonist (Migraine Preparation) Used in the treatment of migraines

1. AstraZeneca Has Been the Target of a Government Investigation

245. In connection with its scheme to inflate AWPs, AstraZeneca has been investigated by the United States Department of Justice. In January 2002, a federal grand jury in Wilmington, Delaware returned an indictment accusing a New Jersey doctor of conspiring with AstraZeneca to resell free samples of Zoladex® that AstraZeneca sales representatives had given the doctor. The indictment alleges that AstraZeneca (i) sold Zoladex® to the New Jersey doctor and others at prices substantially below the AWP reported by AstraZeneca, and (ii) provided the New Jersey doctor with materials showing how much more profit he could make by using Zoladex® instead of its competitor, Lupron®.

246. In response to the government's subpoena, AstraZeneca appears to have produced documents related to Zoladex only.

2. AstraZeneca's Definition and Understanding of AWP

247. In AstraZeneca's Guide to Coverage and Reimbursement, AstraZeneca defines AWP as follows:

> Average Wholesale Price (AWP): The composite wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in either the Red Book or Blue Book. AWP is often used by third-party payers as a basis for reimbursement.

(AZ0052597) (Confidential). Thus, by its own definition, AstraZeneca recognizes that: (i) AWP should be an average of actual wholesale prices; (ii) the drug manufacturers control the published AWP; and (iii) the published AWPs directly affect the payments made by the Class.

3. AstraZeneca Controls the Published AWP for Its Products

248. AstraZeneca has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one internal marketing memorandum, AstraZeneca recommended:

> We take a price increase in December 1995. By doing this, we can inform the Red Book of this increase and it will go into the Red Book for January 1996. This is critical, so that the state Medicare carriers can recognize our new price in January. Typically, the state carriers use the January Red Book and the July Red Book for their reimbursement price of Medicare reimbursed products. Last year when we took the price increase in February there were some Medicare carriers who did not change their reimbursement price until September. Also TAP notifies Red Book 1 month before the price change. We are at a competitive disadvantage with our audience.

(AZ0021838) (Highly Confidential).

4. AstraZeneca's AWP Manipulation Benefited Providers at the Expense of the Class

249. The purpose of AstraZeneca's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

a. In one internal marketing memorandum, AstraZeneca recognized the profits to providers from the inflation of AWPs: "The market we are in wants a more expensive Zoladex, because the doctor can make more money." (AZ0021838) (Highly Confidential).

b. Similarly, in its agreements with PBMs, AstraZeneca guaranteed that it would maintain a spread between AWP and AWC (average wholesale cost) in order to ensure a profit to PBMs at the expense of the Class. (AZ0036207) (Highly Confidential). For example, in its agreement with Caremark, AstraZeneca stated:

> ZENECA WILL REIMBURSE CAREMARK FOR THE DIFFERENCE BETWEEN THE AMOUNT COLLECTED BY CAREMARK ON EACH PATIENT UNIT SOLD AND AWP AT THE TIME THE UNIT WAS DISPENSED. CAREMARK WILL HAVE EXERCISED BEST EFFORTS TO COLLECT THE

> FULL AWP FROM THE 3RD PARTY PAYER AND THE PATIENT PRIOR TO SUBMISSION TO ZENECA.

(AZ0036208) (Highly Confidential).

c. AstraZeneca recognized that its practices were at the expense of the Class:

> BECAUSE OF OUR STEEP DISCOUNTING, NEARLY HALF THE PROFIT TO BE REALIZED WITH ZOLADEX IS PAID BY MEDICARE. AND SINCE MEDICARE IS THE QUICKEST AND MOST DEPENDABLE PAYOR, THIS WAS SEEN AS AN ENORMOUS BENEFIT. THE OTHER HALF OF THE PROFIT WAS FROM THE PATIENT CO PAY OR SECONDARY INSURANCE . . . .

(AZ0037011) (Highly Confidential).

5. AstraZeneca Manipulated and Marketed the AWP for Zoladex

250. AstraZeneca stated an inflated AWP for Zoladex and marketed the resulting spread during the Class Period. AstraZeneca's documents reveal an intense competition with TAP Pharmaceuticals and its drug Lupron, focusing primarily on the spreads available to physicians between Zoladex and Lupron.

251. For instance, one internal chart touts the greater spread that can be reaped from the inflated AWP for Zoladex over the AWP for Lupron:

	AWP	AWP minus 5%	Current Cost (1 depot)	Return to Practice 1 depot	Current Max Discount 29.5% vs 50%	Return to Practice at Max.
Lupron 3-month depot	$1,622.68	$1,541.55	$1,297.50	$244.05	$915.00	$626.55
Zoladex 3-month depot	$1,231.53	$1,169.95	$985.22	$184.73	$492.61	$677.34

(AZ 0055816) (Highly Confidential).

252. Another document announcing new pricing for Zoladex states:

> With a purchase of 72+ depots of ZOLADEX and the additional 2% for paying within 30 days yields the doctor a $133.67 profit margin with ZOLADEX vs $133.50 with a purchase of 101+ depots of Lupron. For those offices that purchase between 60-100 depots of Lupron monthly, they can increase their profit margin greatly by purchasing ZOLADEX.

(AZ 0037019) (Highly Confidential).

253. Moreover, AstraZeneca repeatedly tried to educate providers regarding the Medicare reimbursement system and the benefits to the providers for Zoladex utilization. For example in a document sent to providers AstraZeneca states:

The following is a cost comparison of Zoladex® vs Lupron® 7.5 mg where Zoladex® is purchased under the buying power of the Urology Purchasing Group, St. Louis, Mo. The calculations reflect prices/discounts effective as of 2/1/94.

	ZOLADEX	LUPRON			
Quantity	1	1-11	12-25	26-50	Your Office
Direct Drug Cost	$245.97	$371.00	$360.99	$352.50	$
Medicare $ Claim Medicare Payment to MD	$344.76 x 80.% $275.81	$463.75 x 80% $371.00	$463.75 x 80% $371.00	$463.75 x 80% $371.00	$463.75 x 80% $371.00
Patient / 3rd Party Payment*	$344.76 -275.81 $ 68.95	$463.75 -371.00 $ 92.75	$463.75 -371.00 $ 92.75	$463.75 -371.00 $ 92.75	$463.75 -371.00 $ 92.75
Medicare Claim Direct Drug Cost Total Profit Per Injections	$344.76 -245.97 $ 98.79	$463.75 -371.00 $ 92.75	$463.75 -360.00 $103.75	$463.75 -352.50 $111.25	$463.75 -_____
Difference		$ 6.04	$ 4.96	$ 12.46	$_____
Percent Profit per Injection	40%	25%	29%	32%	__%
Additional Cost outlay of Lupron vs Zoladex (Direct Cost vs Direct Cost)		$125.03	$114.03	$106.53	$_____

ILLUSTRATION: If your office uses between 12 and 25 Lupron® units per month, your total "profit" per injection, over Zoladex, is $4.96 but your additional outlay per Lupron injection is $114.03. This represents and unnecessary tie up of corporation monies. Based on 12 Lupron injections per month, your office has "tied up" $1,368.36 to achieve a "profit" of $59.52. In this example, Zoladex represents a 40% return on investment vs. 29% for Lupron.

* Calculations assume a 100% collection of monies from patient or 3rd party. If Lupron® is used instead of Zoladex® and the 20% is not collected, then the office has lost $23.80 per injection ($92.75 - $68.95 = $23.80).

01-25-0418

(AZ0046085) (Highly Confidential).

254. Internal AstraZeneca documents reveal that AstraZeneca was directly marketing the spread to physicians. A memo announcing price changes for Zoladex states:

> We have raised AWP and AWC by 7% and have increased our discount level higher at all purchasing tiers.
>
> Pricing on Zoladex 3-month is as follows:

Discount		AWP	Cost
1-5 depots	0	1206.49	966.79
6-11 depots	11	1206.49	860.44
12-23 depots	15	1206.49	821.77
24-47 depots	17	1206.49	802.44
48-59 depots	20	1206.49	773.43
60-71 depots	22	1206.49	754.10
72-96 depots	24	1206.49	734.76
96-191 depots	25	1206.49	725.09
192 +	30	1206.49	676.75

> Zoladex AWP has been priced at a 5% premium above 3 times the Zoladex 1-month depot. The discount levels have been increased also.

(AZ 0024566-67.)

255. Thus, at the same time AstraZeneca was raising the AWP for Zoladex, it was lowering the real price to providers (by giving bigger discounts), which served to widen the spread.

256. Another document sets forth the difference between the purchase price and the AWP at various volume levels. Note that even with no volume discount, a provider is still making at least a $71.00 profit per unit on Zoladex ($358.55 - 286.84 = 71.71):

> NEW LOWER CASE QUANTITY DISCOUNT
> ZOLADEX PRICING

UNITS	AWP	COST	DISCOUNT	LESS 2%
1-5	$358.55	$286.84	0%	$281.10
6-11	$358.55	$269.63	6%	$264.24
12-23	$358.55	$261.02	9%	$255.80
24-47	$358.55	$252.42	12%	$247.37
48-59	$358.55	$243.81	15%	$238.93
60-71	$358.55	$235.21	18%	$230.50
72+	$358.55	$229.47	20%	$224.88

(P003060.)

257. The same document goes on to tout the practice's ability to make more profit, or return on investment, by exploiting the AWP scheme:

> Thank you for your time and listening ear on Monday, April 17. As discussed, I am offering a proposal to switch Lupron patients to Zoladex. Zeneca Pharmaceuticals now has new volume pricing, with a 20% maximum discount, for Zoladex. What this will offer the practice is an opportunity to save money, realize a better return on investment, achieve the same profit you currently have with our competitor and free up a substantial amount of working capital. Zoladex will also save the patient money and the system money.
>
> Based on a comparison of Zoladex and Lupron, if 480 depots are used annually Zoladex will save the practice $57,177.60 a year. Your dollar return to the practice is now slightly higher with Zoladex. This rate of return for Zoladex is now 59% compared to Lupron's 39%

(P003058.)

258. Another AstraZeneca document even more explicitly demonstrates to providers how they can profit from the AWP scheme, in excess of $64,000 per year:

ZOLADEX

Direct Pricing	Medicare AWP	$$Return / % Return
72+ $224.88	$358.55	$133.67 59%
72x$224.88=$16,191.38	72x$358.55=$25,815.60	$9,624.24 59%
based on your use of 480 depots annually, with our 2% discount these are the comparisons		
$107,942.40	$172,104.00	$64,161.60 59%

(P003058.)

259. According to a September 2001 GAO report, the discount from AWP for medical providers who purchased AstraZeneca's Zoladex and billed Medicare was between 21.9% and 22.3%. ("Payments for Covered Outpatient Drugs Exceed Providers' Cost, Sept. 2001" (P005546-78).)

260. AstraZeneca, through its employees and agents, also provided millions of dollars worth of free samples of its drugs to providers. The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class. Moreover, at least as to Zoladex®, AstraZeneca sales representatives specifically told providers that they could and should bill for the free samples.

261. A written proposal from AstraZeneca Sales representative Randy Payne dated July 17, 1995 encourages a urology practice to switch all of their patients to Zoladex and states: "AS AN ADDED INCENTIVE, ZENECA WILL PROVIDE YOU WITH 50 FREE DEPOTS (over $11,900 worth of product) FOR THE INITIAL CONVERSION TO ZOLADEX." (P003059.)

262. As set forth above, AstraZeneca's scheme to inflate its reported AWPs for Zoladex, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

D. The Aventis Group (Aventis, Pharma, Hoechst and Behring)

263. Aventis engages in an organization-wide and deliberate scheme to inflate AWPs. Aventis has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Aventis for which relief is sought in this case are set forth in Appendix A or in the proposed class certification order, and are summarized below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
AVENTIS GROUP (Aventis, Pharma, Hoechst and Behring)	Allegra	fexofenadine	Antihistamine Used for the relief of symptoms of seasonal allergic rhinitis
	Allegra-D	fexofenadine pseudoephedrine	Antihistamine Used for the relief of symptoms of seasonal allergic rhinitis

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Amaryl	glimepiride	Antidiabetic Used to lower blood glucose in Type II diabetes patients
	Anzemet	dolasetron mesylate	Antineoplastic Used to prevent nausea and vomiting after chemotherapy or operation
	Arava	leflunomide	Antirheumatic Used in the treatment of active rheumatoid arthritis
	Azmacort	triamcinolone aceonide (inh)	Steroidal Anti-Inflammatory Agent (Respiratory Agent) Used for maintenance treatment of asthma
	Calcimar	calcitonin salmon	Parathyroid Agent Used in the treatment of blood calcium levels and to increase the level of calcium in the bones
	Carafate	sucralfate	Duodenal Ulcer Adherent Complex (Gastrointestinal Agent) Used in the treatment and maintenance therapy of duodenal ulcer
	Cardizem	diltiazem	Calcium Channel Blocker (Cardiovascular Agent) Used in the treatment of angina and hypertension
	Gammar PI.V.	immune globulin	Immunizing Agent Used as a maintenance therapy in patients with compromised immune systems
	Intal	cromolyn sodium	Antiasthmatic Used to treat allergic rhinitis and severe perennial bronchial asthma
	Nasacort	triamcinolone acetonide (nasal)	Steriodal Anti-Inflammatory Agent (Nasal Preparation) Used for nasal treatment of allergic rhinitis symptoms
	Taxotere	docetaxel	Antineoplastic Used in the treatment of breast or lung cancer after failed chemotherapy
	Trental	pentoxifylline	Blood Viscosity-Reducing Agent (Blood Modifier) Used to improve the flow of blood through blood vessels

1. Aventis Has Been the Target of Government Investigations

264. In connection with its scheme to inflate AWPs, Aventis has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Commerce Committee of the U.S. House of Representatives, the Attorney General for the State of Texas, the Attorney General for the State of California, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse.

2. Aventis' Definition and Understanding of AWP

265. Internal documents recently produced by Aventis reveal the definition of AWP used and understood by Aventis and its predecessor companies. Specifically, a November 1992 internal newsletter at Armour Pharmaceutical Company (a predecessor company to Centeon LLC, later known as Aventis Behring) states:

> "AWP" is common language among insurance carriers (state, federal and private). The acronym stands for Average Wholesale Price. AWPs are set by manufacturers as a "suggested retail" for the products they produce. ***These figures represent a reasonable profit margin to healthcare providers and as such are widely referenced by insurance carriers when setting reasonable and customary rates of reimbursement***.
>
> Average Wholesale Prices are printed in Red Book Drug Topics and Blue Book. Both serve as data resources to all state Medicaid programs. Each publication lists the drugs by brand name in alphabetical order with its corresponding descriptions.

(ABAWP 008990-91) (Highly Confidential) (emphasis added).

266. Aventis possessed the *Red Book*'s definition of Average Wholesale Price:

> Average wholesale price (AWP) is the standardized cost of a drug, which managed care plans frequently use for determining drug benefits. The AWP is determined through reference to a common source of price information, such as the American Druggist's *Blue Book*, which lists the costs charged for an undiscounted drug to a pharmacy by a large group of pharmaceutical wholesale suppliers. AWP's are set by pharmaceutical manufacturers and supplied to all pricing data banks for publication.

(ABAWP 012067) (Highly Confidential).

3. Aventis Controls the Published AWP for Its Products

267. Aventis controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

a. For example, on December 29, 1997, Rhone-Poulenc Rorer (a subsidiary of Rhone Poulenc SA, which merged with Hoechst AG to form Aventis in 1999) submitted a list of AWP price increases effective January 1, 1998 to both Medi-Span and First Data Bank. Aventis instructed Medi-Span and First Data Bank to "change [their] records accordingly to reflect the new prices." (AV-AAA-001054) (Confidential). Similar letters requesting price changes for 1999 were sent to Medi-Span and First Data Bank by Aventis on December 29, 1998. (AV-AAA-001047) (Highly Confidential), (AV-AAA-001050) (Highly Confidential), and price changes for 1997 on December 23, 1996 (AV-AAA-001066) (Highly Confidential).

b. An April 1, 1998 letter from Centeon notifies Medical Economics (the *Red Book*) that effective April 1, 1998, it "has raised AWP pricing" for Bioclate and Monoclate. (ABAWP 005314) (Highly Confidential).

4. Aventis' AWP Manipulation Benefited Providers at the Expense of the Class

268. The purpose of Aventis' manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

269. Aventis knew that AWP manipulation, and the related marketing of an AWP spread, was improper. An internal Aventis (Centeon) document, in pertinent part, states – in large, bold print:

> **ATTENTION!**
>
> SELLING AGAINST AWP
>
> This is <u>not</u> an option.
>
> Traditionally, some manufacturers have promoted differences in AWPs as a means to sell their products. Centeon does not do this,

> and we hope to hear from you if you learn that any other manufacturer (sic) are using this tactic.
>
> Some pharmaceutical manufacturers set high AWPs as a means of securing market shares for their drugs. Although not illegal, the intensity of government scrutiny of this and other pharmaceutical manufacturer pricing practices is increasing. The inspector general is looking at prices for big-ticket drugs
>
> ***
>
> At the risk of being redundant it is imperative to stress that AWP can not (sic) be used in the content of selling any of our products. If you are made aware, either orally or through written correspondence, of an1y manufacturer using this form of sales tactic immediately report such findings to Gene Hull and appropriate steps will be taken.

(ABAWP 000855) (Highly Confidential).

270. Nonetheless, Aventis (Centeon) routinely promoted differences in AWPs in marketing its numerous products. In seminar materials used in conjunction with an "Oncology University Anzemet Workshop" held in 1998, Aventis explained to attendees how its AWP spread could be exploited. Aventis offered the following definition and example of AWP spread:

> **SPREAD**
>
> - Difference between acquisition cost (AC) and reimbursement (Profit, Margin, etc.).
> - Example for Anzemet
>
> -AC = $68 for 100 mg vial
> -AWP = $166.50
> -AWP – 5% = $158.18
> -80/20 = $126.54/$31.64
> -Spread = $58.54 + $31.64 = $90.18

(AV-AAA-02242-56) (Highly Confidential).

271. Aventis, through its employees and agents, also provided free samples of its drugs to providers. (ABAWP 000089) (Highly Confidential) (ABAWP 000811) (Highly Confidential). The free samples would be used to offset the total cost associated with purchases of its drugs,

thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class. In fact, a 1995 "SALES AND FREE GOODS STATUS" memo reveals that Aventis (Armour) issued millions of "free goods units" to a single customer alone. (ABAWP 000220-25) (Highly Confidential).

272. Further, just as Aventis motivates providers to administer drugs based on the AWP, Aventis rewards PBMs based on the degree of influence they exert to drive utilization of Aventis products. (AV-AAA-000197-99) (Highly Confidential).

5. Specific Aventis AWPs Documented by the DOJ

273. In a report published by the DHHS (AB-00-86), the DOJ documented at least 15 instances where the published AWPs for various dosages of 4 drugs manufactured by Aventis were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 4 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Aventis in the 2001 *Red Book*.

Drug	2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Anzemet Injectable (dolasetron mesylate)	$166.50	$74.08	$92.42	125%
Factor VIII/ Bioclate	$1.25	$.91	$.34	37%
Factor VIII/ Helixate	$1.18	$.78	$.40	51%
Gammar (immune globulin)	$400.00	$296.67	$103.33	35%

(P006299-P006316).

274. An OIG report (*see* "Medicare Reimbursement of Prescription Drugs," OEI-03-00-00310, Jan. 2001) further revealed that: (i) the AWP for all immune globulin 5 mg doses listed in the 1997 *Red Book* were inflated by an average spread of 32.21%; (ii) a 10 mg dose of Anzemet had a Medicare Median of $14.82 and a Catalog Median of $8.29, resulting in a spread

of 78.76%; and (iii) a 20 mg dose of Taxotere had a Medicare Median of $283.65 and a Catalog Median of $8.29, resulting in a spread of 18.75%. (P006398-006424).

6. Additional Evidence Concerning Anzemet

275. Aventis distributed a "Reimbursement Spreadsheet" to be utilized by its sales personnel to demonstrate to "private practice office" customers the "financial advantages" of its drug, Anzemet, compared to Zofran and Kytril based on Aventis' established AWP and acquisition price (total reimbursement through Medicare). (AV-AAA-001190-93) (Highly Confidential). Aventis also communicated to its sales staff on December 7, 1998 that "Anzemet still [held] the advantage on spread" following a Kytril price increase. (AV-AAA-002291) (Highly Confidential).

276. Another Aventis internal document also addresses how a particular Aventis customer might increase its margin choosing Anzemet over the competition:

> Cost and Reimbursement: OnCare has negotiated a very favorable contract with Hoechst Marion Roussel [an Aventis predecessor company], manufacturer of Anzemet. Our cost from OTN for the Anzemet 100 mg/ml vial is reduced from approximately $70 ea. to $62.50. In addition there will be quarterly rebates further reducing the cost to $61.25. The AWP is $149.88, making the margin $88.63. Additional returns can be realized by using 1.8 mg/kg as recommended in the package insert. For example, for a patient weighing 70Kg, the dose is 126 mg, requiring 2 vials. Since the vial is single use, you may bill for both vials: total cost is $122.50, the AWP is $299.76, the net is $177.26 (assuming reimbursement at AWP). By comparison the current margin for 0.7 of Kytril is $54.89. For 1 mg it is $78.42. If there is a price increase in 1999 (which we expect) our prices are protected, however the AWP will go up, further increasing the margin. The contract makes Anzemet the preferred 5-HT3 antiemetic drug for OnCare.

(AV-AAA-001523) (Highly Confidential). Other customers received promotional materials reflecting a significant spread between the unit price and AWP for Anzemet – and touting a "Reimbursement and Patient Assistance Program Hotline." (AV-AAA-001619-23) (Confidential).

277. A government investigation revealed similar inflated pricing implemented by Aventis with respect to the injectable form of Anzemet. In a September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, U.S. Rep. Pete Stark provided a synopsis of the scheme implemented by Aventis (Hoechst):

> The following chart represents a comparison of Hoechst's fraudulent price representations for its injectable form of the drug versus the truthful prices paid by the industry insider. It is [sic] also compares Hoechst's price representations for the tablet form of Anzemet and the insider's true prices. It is extremely interesting that Hoechst did not create a spread for its tablet form of Anzemet but only the injectable form. This is because Medicare reimburses Doctors for the injectable form of this drug and by giving them a profit, can influence prescribing. The tablet form is dispensed by pharmacists, who accept the Doctor's order. And this underscores the frustration that federal and state regulators have experienced in their attempts to estimate the truthful prices being paid by providers in the marketplace for prescription drugs and underscores the fact that, if we cannot rely upon the drug companies to make honest and truthful representations of their prices, Congress will be left with no alternative other than to legislate price controls.

NDC No:	Unit Size/ Type	Quantity	Net Price as Represented to Florida Medicaid	True Wholesale Price	Variance
0088-1206-32	100 mg/5 ml Injectable	1	$124.90	$70.00	Represented price 78% higher than true wholesale price.

(P007548-007588).

7. Additional Evidence Concerning Gammar

278. Similarly, Aventis increased AWPs for its Gammar product line to keep provider and intermediary reimbursement levels competitive with those created by the inflated AWPs of other manufacturers. A May 8, 1996 Aventis (Centeon) Interoffice Correspondence memo states:

> Effective June 1, 1996, we will be revising our AVERAGE WHOLESALE PRICE for our Gammar P iv product line. We are implementing this change based on feedback from the field. Alpha and Bayer have recently increased their AWP pricing on

> Gammimmune 10% and Venoglobulin S 10%. They are presently priced at $75 and $80 per gram respectively. . . . This change will help us maintain a competitive balance in the marketplace.

(ABAWP 004767) (Highly Confidential).

279. Centeon interoffice correspondence, dated June 23, 1999, reveals that a Centeon employee provided a representative of First Data Bank with the following information regarding Centeon's AWP for Gammar:

> She asked me to validate Centeon's AWP and wholesale list price for Gammar PIV 5 and 10 gram vials.
>
> ***
>
> I gave her the following info:
>
> "Currently it is not Centeon's business practice to sell Gammar PIV to wholesalers. But should a wholesaler place an order, our wholesale list price is $52/gram, or $260 for 5 gram vial, and $520 for 10 gram vial."
>
> "Centeon's suggested AWP is $400 for 5 gram vial, and $800 for 10 gram vial. This is pricing as reported to First Data Bank, but we do not sell product at these prices."

(ABAWP 005315) (Highly Confidential).

280. U.S. Rep. Thomas J. Bliley, in a May 4, 2000 letter to the CEO of Aventis (Behring), also stated concerns regarding Aventis' pricing of Gammar:

> The Office of Inspector General (OIG) at the Department of Health and Human Services determined that the Medicare-allowed amount for immune globulin, a pharmaceutical product sold by your company under the name Gammar, in Fiscal Year 1996 was $42.21. The OIG further estimated that the actual wholesale price of this drug was $16.12 and the highest available wholesale price that the OIG was able to identify was $32.11.

(P006962-P006966).

8. Inflated AWPs From Aventis' Price Lists

281. In response to government subpoenas, Aventis produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other

intermediaries. A review of those price lists reveals that Aventis has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical.

282. A March 4, 1997 price list issued by Arcola Laboratories (a division of Rhonel-Poulenc Rorer Pharmaceuticals sets the AWP for Calcimar (calcitonin-salmon) at $31.35, with a cost of $12.00 – for a spread of 161%. (AV-AAA-000705).

283. As set forth above, Aventis' scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

9. Aventis Concealed its AWP Manipulation

284. Aventis deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, in response to a May 26, 1995 fax request from *Red Book*, Aventis refused to provide Wholesale Acquisition Cost (WAC) for products it listed in the *Red Book* database – in spite of *Red Book's* assurances that WAC information would be distributed via electronic means only. (ABAWP 008420) (Highly Confidential). Aventis effectively hid the AWP spread from Plaintiffs and the Class.

E. Baxter

285. Baxter engages in an organization-wide and deliberate scheme to inflate AWPs. Baxter has stated fraudulent AWPs for all or almost all of its drugs those set forth below. The specific drugs of Baxter for which relief is sought in this case are set forth in Appendix A or in the proposed class certification order, and are summarized below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BAXTER	Aggrastat	tirofiban hydrochloride	Glycoprotein Receptor Inhibitor (Blood Modifier) Used in the treatment of acute coronary symptoms
	Ativan	lorazepam	Antianxiety Agent (Psychotherapeutic Agent); Anticonvulsant Used to relieve anxiety and treat insomnia
	Bebulin VH	factor ix (systemic)	Antihemorrhagic Agent Used to treat hemophilia B
	Brevibloc	esmolol hcl	Autonomic Nervous System Agent Used in the treatment of tachyarrhythmias in critical situations
	Buminate	albumin (human)	Plasma Fraction (Blood Modifier) Used in the treatment of hypovolemia and hypoalbuminemia
	Claforan	cephalosporin (systemic)	Antibacterial Agent (Anti-Infective Agent) Used in the treatment of infections caused by bacteria
	Gammagard S/D	immune globulin solution	Antibacterial Agent (Anti-Infective Agent) Used to prevent or treat some illnesses.
	Gentran	dextran	Blood Derivative; Blood Modifier Used in the emergency treatment of shock
	Holoxan/Ifex	ifosfamide	Antineoplastic Used in the treatment of various forms of cancer
	Iveegam EN	immune globulin iv	Antibacterial Agent (Anti-Infective Agent) Used as replacement therapy in patients with primary immunodeficiency syndromes
	Osmitrol	mannitol	Osmotic Diuretic Used to promote diureses during treatment of acute kidney failure. Also used to reduce intraocular and intracranial pressure
	Recombinate	factor viii	Antihemophilic Factor Used to induce blood clotting
	Travasol	amino acid	Dietary Supplement Used for nutritional support in cancer patients
	Vancocin HCl	vancomycin hydrochloride	Antibacterial Agent (Anti-Infective Agent) Used in the treatment of infections caused by bacteria
		cisplatin	Antineoplastic Used to treat cancer of the bladder, ovaries, and testicles
		dextrose	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		doxorubicin hcl	Antineoplastic Used in the treatment of various forms of cancer
		gentamicin	Antibacterial Agent (Anti-Infective Agent) Used to treat serious bacterial infections
		heparin	Anticoagulant (Cardiovascular Agent) Used to decrease the clotting ability of the blood
		sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion

1. Baxter Has Been the Target of Government Investigations

286. Baxter has been investigated by the United States Department of Justice, Department of Health and Human Services Office of Inspector General, the Attorney General for the State of California, the Attorney General for the State of Texas, the Attorney General for the State of Illinois, and the Committee on Commerce of the House of Representatives.

287. These investigations confirm that Baxter has engaged in a deliberate scheme to inflate AWPs for many or most of its drugs. A Baxter document made public as a result of the congressional investigation entitled, "Confidential – Baxter Internal Use Only," acknowledged that: "Increasing AWPs was a large part of our negotiations with the large homecare companies." Baxter further admitted in internal documents that homecare companies that reimburse based on AWP make a significantly higher margin. Thus, Baxter's own documents demonstrate its active participation in the scheme to artificially inflate AWPs.

2. Baxter's Definition and Understanding of AWP

288. Despite its manipulation, Baxter understood what AWP should mean: "The average price that a pharmacy (or provider) pays for the product from their drug wholesaler or distributor." (BAX MDL 0011378) (Highly Confidential). Contrary to its own definition of

AWP, Baxter nonetheless set AWPs for its drugs far in excess of what providers paid for those drugs.

3. Baxter Controls the Published AWP for its Products

289. Baxter has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, a September 7, 1995 inter-office memorandum provides:

> I have been in contact with both *Red Book* and Medispan earlier this year about our AWPs. I told them that we will not be raising our AWPs for FVIII in 1995, and will only increase IGIV in the event of a label change. There are a few general rules about AWP adjustments.
>
> • A manufacturer may raise AWPs at any time in the year. There is a monthly publication called the *Red Book* Update that lists all changes to the April publication (the big red book).
>
> • If a manufacturer does decide to increase AWPs: - payors want a justification for the increase. This is why we typically don't increase the AWP unless we have a label change, product enhancement . . . .

(BAX MDL 0004754) (Highly Confidential).

4. Baxter's AWP Manipulation Benefited Providers at the Expense of the Class

290. In at least one internal document, Baxter recognized that deliberate manipulation of the spread was being wrongly used to gain competitive advantage by manufacturers:

> ***The deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition cost and AWP/WAC is direct profit for customers, and is being used to increase product positioning in the market by certain manufacturers.***

(BAX MDL 0012778) (Highly Confidential) (emphasis added).

291. Despite this recognition, Baxter nonetheless continued to manipulate its AWPs in order to maintain the competitiveness of its own products based upon the spread. In a January 6,

1992 inter-office memorandum, Baxter informs its employees how to respond to inquiries concerning AWP increases for Baxter products:

> If you receive inquiries from customers or payors questioning our rationale on this recent increase in Published AWP for Baxter products please communicate the following message and no more.
>
> If any further information is needed please send the inquiry to me directly.
>
> A recent review of industry published direct prices and AWPs revealed that Baxter's published AWPs are significantly lower than competitive AWPs. We have therefore adjusted our AWPs to meet competitive levels.
>
> Most of Baxter General Healthcare Division's products are sold to distributors at negotiated contract prices that are different from AWPs. We do not have knowledge of or input to the actual prices charged to the provider by our distributors. The contracted prices to our distributors will not be directly affected by this change in AWPs.

(BAX MDL 0004210) (Highly Confidential).

292. In addition, Baxter's marketing and sales documents, which were prepared and disseminated to its employees and agents via the U.S. mail and interstate wire facilities, compared the costs of their respective drugs to those of their respective competitors and were intended to induce physicians to use Baxter drugs and shift market share in its favor. Other documents created and disseminated by Baxter compared the AWP and the actual "cost" of their respective drugs, so that medical providers could easily see the different "return-to-practice" amounts available for different levels of purchase.

5. Specific Baxter AWPs Documented by the DOJ

293. In a report published by the DHHS (AB-00-86), the DOJ documented at least 41 instances where the published AWPs for various dosages of drugs manufactured by Baxter were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the four drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular

dosage, based upon wholesalers' price lists, with the AWP reported by Baxter in the 2001 *Red Book*.

Drug in Lowest Dosage Form	Baxter's 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Dextrose	$928.51	$2.25	$926.26	41,167%
Dextrose Sodium Chloride	$357.69	$2.93	$354.76	12,108%
Sodium Chloride	$928.51	$1.71	$926.80	54,199%
Factor VIII	$1.28	$.92	$.36	39%

(P006299-006316).

6. Evidence Concerning Gammagard S/D (immune globulin solution)

294. Baxter admittedly manipulated the AWP for Gammagard S/D. In 1996, Baxter distributed a memo providing "[t]he deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition cost and AWP/WAC is a direct profit for customers, and is being used to increase product positioning in the market by certain manufacturers." Immediately below this text is a handwritten note reading "[w]ill raise AWP for GG/SD by 15%." (BAX MDL 0012778) (Highly Confidential).

295. According to Baxter's own documents, the published AWPs for Gammagard S/D were higher than the actual prices provided to wholesalers. In a customer announcement dated September 24, 1996, Baxter increased the AWP for one particular dosage of Gammagard S/D from $640.71 to $737.00, and the WAC from $365.00 to $420.00. The difference between the new AWP and the new WAC ($317.00) constituted a 43% spread. (BAX MDL 005366) (Highly Confidential).

7. Inflated AWPs From Baxter's Price Lists

296. In response to government subpoenas, Baxter produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Baxter has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the

published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1 and 2 are a number of those drugs (not already referenced above) with spreads between the AWPs and direct prices. Table 1 is an analysis of certain dosages of Baxter drugs from a document entitled "Baxter Healthcare Corporation Intravenous and Irrigation Solution Products Report" (BAX MDL 0003428-46) (Highly Confidential)).

Table 1

Drug	AWP	DP	Difference	% Spread
Ringers	10.84	6.34	4.50	71%
Lactated Ringers	12.36	7.43	4.93	66%
Plasma-lyte 148	15.67	10.85	4.82	44%
5% Travert and electrolyte no. 2	16.39	11.30	5.09	45%
6% Gentran75	73.46	33.19	40.27	121%
Sterile Water	9.97	6.15	3.82	62%
Sodium Lactate	17.98	11.11	6.87	62%
Osmitrol	70.28	35.12	35.16	100%
Gentamycin	10.78	7.25	3.53	49%
Metronidazole injection	15.34	7.85	7.49	95%
Rocephin	40.18	32.67	7.51	23%
Nitroglycerin	17.37	9.82	7.55	77%
Potassium Chloride Injection	14.63	10.16	4.47	44%
Dopamine	19.30	13.40	5.90	44%
Lidocaine	22.74	13.48	9.26	67%
Heparin	9.94	6.49	3.45	53%
Theophylline	11.45	7.81	3.64	47%
Glycine for Irrigation	32.87	19.70	13.17	67%
Tis-U-Sol	22.73	11.36	11.37	100%
Acetic Acid	20.70	10.91	9.79	90%
Irrigating Solution G	16.67	11.04	5.63	51%
Balanced Salt Solution	28.76	15.00	13.76	92%
Sodium Bicarbonate	39.23	16.36	22.87	140%

297. Table 2 is an analysis of certain dosages of Baxter drugs from a document entitled "IV Nutrition Products" (BAX MDL 0003421-26) (Highly Confidential).

Table 2

Drug	AWP	DP	Difference	% Spread
Novamine Injection	95.14	51.48	43.66	85%
Travasol	83.44	40.21	43.23	108%
RenAmin Injection	75.00	48.00	27.00	56%

Aminess Essential Amino Acid	107.35	66.00	41.35	63%
BranchAmin Injection	93.60	60.00	33.60	56%

8. Baxter Provided Free Goods and Other Incentives

13. Baxter also provided physicians with free goods with the understanding that physicians would bill for those goods, in violation of federal law. Billing for free goods was a way for physicians to obtain greater profit at the expense of the Class. Baxter's fraudulent use of free goods aimed at increasing market share is evidenced by an internal memorandum from a Baxter contract administrator to certain field sales managers encouraging the distribution by U.S. mail or otherwise of free product to achieve overall price reduction:

> BAXTER: "The attached notice from Quantum Headquarters was sent on April 10th to all their centers regarding the reduction on Recombinate pricing. Please note that they want to continue to be invoiced at the $.81 price. They have requested that we send them free product every quarter calculated by looking at the number of units purchased in that quarter and the $.13 reduction in price . . . free product given to achieve overall price reduction."

Letter from Stark, Committee on Ways and Means to Holman, Pres. Pharmaceutical Research and Manufacturers of America, Sept. 28, 2002 (P0075410-44).

298. As set forth above, Baxter's scheme to inflate its reported AWPs, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

F. Bayer

299. Bayer engages in an organization-wide and deliberate scheme to inflate AWPs. Bayer has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Bayer for which relief is sought in this case are set forth in Appendix A, and are set forth below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BAYER	Cipro	ciprofloxacin or ciprofloxacin hcl	Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various bacterial infections, including anthrax
	Cipro XR	ciprofloxacin hcl-ciprofloxacin betaine	Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various bacterial infections, including anthrax
	DTIC-Dome	dacarbazine	Antineoplastic Used in the treatment of melanoma and Hodgkin's disease
	Gamimune N	immune globulin (human) iv	Immunizing Agent Used as maintenance therapy in patients with compromised immune systems
	Koate-HP	antihemophilic factor (human)	Antihemophilic Factor (Blood Modifier) Used to increase blood clotting and decrease bleeding episodes
	Kogenate	antihemophilic factor (recombinant)	Antihemophilic Factor (Blood Modifier) Used to increase blood clotting and decrease bleeding episodes
	Mithracin	plicamycin	Antineoplastic; Antihypercalcemic Agent Used in the treatment of various forms of cancer

1. Bayer Has Been the Target of Government Investigations

300. In connection with its scheme to inflate AWPs, Bayer has been investigated by the Department of Justice, Department of Health and Human Services, Office of Inspector General, and the Commonwealth of Massachusetts. Bayer agreed to settle claims asserted by the United States government and 47 states arising from its fraudulent pricing and marketing practices. According to the DOJ's January 23, 2001 press release:

> The government's investigation of the allegations…revealed that [Bayer] beginning in the early 1990s, falsely inflated the reported drug prices – referred to by the industry as the Average Wholesale Price (AWP), the Direct Price and the Wholesale Acquisition Cost – used by state governments to set reimbursement rates for the Medicaid program. By setting an extremely high AWP and, subsequently, selling drugs at a dramatic discount, Bayer induced physicians to purchase its products rather than those of competitors by enabling doctors to profit tremendously from reimbursement paid to them by the government.

> The Bayer AWPs at issue in the investigation involved Bayer's biologic products such as Kogenate, Koate-HP, and Gamimmune, which are widely used in treating hemophilia and immune deficiency diseases. The investigation further revealed that the practice in which Bayer selectively engaged, commonly referred to as "marketing the spread," also had the effect of causing other drug companies to inflate their AWPs.

"Bayer Corporation Settlement on Medicaid Drug Prias" (P011236-011237).

301. As part of its settlement of government claims in 2000, Bayer is required, under the terms of a corporate integrity agreement, to provide state governments and the federal government with the average selling prices of its drugs – a price which accounts for all discounts, free samples, rebates and all other price concessions provided by Bayer to any relevant purchaser that result in a reduction of the ultimate cost to Bayer's customers.

302. In April 2003, Bayer also agreed to pay the government $251.6 million in civil penalties for violating the Federal Prescription Drug Marketing Act for alleged overcharges involving its antibiotic Cipro and its high blood pressure drug Adalat.

2. Bayer Controls the Published AWP for Its Products

303. Bayer has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one internal marketing memorandum, Bayer stated:

> I would like to formally request that you contact Redbook and request an AWP change for all sizes (670-20, 670-30, 670-50) of Kogenate from $1.18 per IU to $1.24 per IU to match Baxter's increase. I have attached a letter from Baxter to Redbook outlining their price change request. (Prior to making the change in AWP for Kogenate, please confirm with Redbook that Baxter has indeed initiated a price change.)

(BAY005278) (Highly Confidential).

3. Bayer's AWP Manipulation Benefited Providers at the Expense of the Class

304. As detailed in a September 28, 2000 letter from Representative Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, internal Bayer

documents reveal Bayer knowingly participated and directed the scheme to artificially inflate the AWPs for its products and to market the spread:

> BAYER: "Chris, if Baxter has increased their AWP then we must do the same. Many of the Homecare companies are paid based on a discount from AWP. If we are lowed [sic] than Baxter then the return will be lower to the HHC. It is a very simple process to increase our AWP, and can be done overnight."

(P007549.)

305. Tom Bliley, in a letter dated September 25, 2000 to the Health Care Financing Administration, analyzed drug sales in Florida and noted that sales of Bayer's WhinRho "skyrocketed" when competitors reduced their spreads but Bayer did not.

4. Specific Bayer AWPs Documented by the DOJ

306. In a report published by the DHHS, the DOJ documented at least 10 instances where the published AWPs for various dosages of two drugs manufactured by Bayer were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the two drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Abbott in the 2001 *Red Book*.

Drug	Bayer's 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Immune Globulin	$450.00	$362.50	$87.50	24%
Factor VIII	$0.92	$0.42	$0.50	119%

(AB-00-86 (P006299-006316)).

307. In a DHHS OIG report (*see* OEI-03-00-00310 (P006398-006424)), the government also discovered that the AWP for all immune globulin pharmaceuticals (of a dosage of 5g), including Bayer's Gamimune® (Bayer was one of five manufacturers of the dosage listed in the 1997 *Red Book*), were over inflated by an average spread of 32.21%.

308. According to the government's settlement with Bayer arising out of Bayer's fraudulent pricing and marketing practices, the Bayer AWPs at issue in the investigation (and ultimately settled) include the AWPs for Kogenate.

5. Inflated AWPs From Bayer's Price Lists

309. According to Bayer's own documents, the published AWPs for its drugs were higher than the actual prices provided to wholesalers. In response to government subpoenas, Bayer produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Bayer has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

6. Bayer Provided Free Goods and Other Incentives

310. In addition to marketing the spread, Bayer has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Bayer provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

311. Evidence of these practices is found in an October 1, 1996 Bayer internal memorandum addressing volume sales opportunities for the pharmaceutical Kogenate®:

> BAYER: "I have been told that our present Kogenate price, $.66 is the highest price that Quantum is paying for recombinant factor VIII. In order to sell the additional 12mm/u we will need a lower price. I suggest a price of $.60 to $.62 to secure this volume. From Quantum's stand [sic] point, a price off invoice, is the most desirable. We could calculate our offer in the form of a marketing grant, a special educational grant, payment for specific data gathering regarding Hemophilia treatment, or anything else that will produce the same dollar benefit to Quantum Health Resources."

312. As set forth above, Bayer's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

313. Bayer routinely offered its customers off-invoice discounts as one feature of its standard contracts. (BAYM002428).

7. Bayer Concealed Its AWP Manipulation

314. Bayer deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. Bayer routinely required that its customers keep secret the prices they were being charged for Bayer drugs. (BAYM000913, BAYM002436).

G. The BMS Group (Bristol-Myers, OTN and Apothecon)

315. The BMS Group has engaged in an ongoing deliberate scheme to inflate AWPs. The specific drugs for which relief is sought in this case are identified in Appendix A and are as follows:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BMS GROUP (Bristol-Myers, OTN and Apothecon)	Avapro	irbesartan	Antihypertensive Agent Used to treat hypertension
	Blenoxane	bleomycin sulfate	Antineoplastic Used in the treatment of various forms of cancer
	Buspar	buspirone hcl	Antianxiety Agent (Psychotherapeutic Agent) Used to treat certain anxiety disorders or to relieve the symptoms of anxiety
	Carboplatin	paraplatin	Antineoplastic Used to treat cancer of the ovaries
	Cefzil	cefprozil	Antibacterial Agent (Anti-Infective Agent) Used in the treatment of infections caused by bacteria
	Coumadin	warfarin sodium	Anticoagulant (Blood Modifier) Used to promote clotting
	Cytoxan	cyclophosphamide	Antineoplastic Used in the treatment of various forms of cancer

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Etopophos	etoposide phosphate	Antineoplastic Used to treat cancer of the testicles and certain types of lung cancer
	Glucophage	meformin hcl	Antihyperglycemic Agent Used to treat a type 2 diabetes mellitus.
	Monopril	fosinopril sodium	Antihypertensive Agent; Vasodilator (Cardiovascular Agent) Used to treat hypertension
	Monopril HCT	fosinopril sodium & hydrochloro-thiazide	ACE Inhibitor (Cardiovascular Agent) Used in the treatment of hypertension and congestive heart failure
	Plavix	clopidogrel bisulfate	Antithrombotic Agent Used to lessen the chance of heart attack or stroke
	Rubex	doxorubicin hcl	Antineoplastic Used in the treatment of various forms of cancer
	Serzone	nefazodone hcl	Antidepressant (Psychotherapeutic Agent) Used to treat mental depression
	Taxol	paclitaxel	Antineoplastic Used in the treatment of various forms of cancer
	Tequin	gatifloxacin	Antibacterial Agent (Anti-Infective Agent) Used to treat bacterial infections
	Vepesid	etoposide	Antineoplastic Used to treat cancer of the testicles and certain types of lung cancer
	Videx EC	didanosine	Antiviral Agent (Anti-Infective Agent) Used in the treatment of HIV infection
		amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
		amphotercin b	Antifungal Agent (Anti-Infective Agent) Used to help the body overcome serious fungus infections

1. The BMS Group Has Been the Target of Government Investigations

316. In connection with its scheme to inflate AWPs, BMS has been investigated by the United States Department of Justice, Commonwealth of Massachusetts, Office of Inspector General of the U.S. Department of Health and Human Services, Attorney General for the State of Texas, State of California Department of Justice Office of the Attorney General, State of California Department of Justice, Bureau of Medi-Cal Fraud and Elder Abuse, and the U.S.

House of Representatives, Committee on Commerce. Defendant Apothecon has been investigated in connection with its scheme to inflate AWPs by at least the Office of Medicare Fraud and Elder Abuse, Office of Attorney General, State of Texas.

317. These investigations confirm that BMS engaged in an ongoing deliberate scheme to inflate AWPs. For example, by letter dated February 27, 2001 to BMS, Rep. Stark outlined numerous examples of illegal practices by BMS. Referring to a letter from Denis Kaszuba, a senior pricing analyst at BMS to Medispan, dated August 10, 1992 (BMSAWP/0011247), Rep. Stark noted:

> Bristol has control over the AWPs, DPs, and WACs published for its drugs and directs national publishers to change their prices. Bristol directed a national publisher of drug prices to increase all of Bristol's AWPs for oncology drugs by multiplying Bristol's supplied direct prices by a 25% factor rather than the previous 20.5% factor . . . The increase in the AWP created a spread that, in itself, provided a financial kickback to oncologists for prescribing Bristol's cancer drugs.

318. In the same letter, Rep. Stark noted:

> The evidence clearly shows that Bristol has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Bristol manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs where the arranging of a financial benefit or inducement would influence the decisions of healthcare providers submitting the Medicare and Medicaid claims.

2. The BMS Group Controls the Published AWP for Its Products

319. The BMS Group has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one BMS document, Denise Kaszuba, a senior BMS Group pricing analyst, instructed the *Red Book* that:

> Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%. This change should not effect [*sic*] any other business unit of Bristol-Myers Squibb Company.

320. Other internal documents clearly indicate that BMS had direct control over the spread between its states wholesale price and the published AWP. A BMS office dispatch dated September 9, 1992 notes the need for a mark up of the AWP over the state wholesale price. "After reviewing the results of the wholesaler survey performed by Bristol Oncology . . we have determined that for those items with a labeler 0003, we will use a 1.25 mark-up and for those items with the labeler 00015, we will use a 1.20 mark-up. We noticed too, that FDB and Redbook use a 1.20 for everything." (BMSAWP/0011246).

3. BMS's AWP Manipulation Benefited Providers at the Expense of the Class

321. BMS was well aware that providers and other purchasers of its drugs were using the spread to determine whether to purchase its drugs. Indeed, BMS was aware of and tracked the prices and AWPs of its competitors in order to remain competitive. In an internal BMS memorandum, BMS identifies its competitors who sell etoposide (Gensia, Pharmacia, Abbott, Chiron, Ben Venue, Immunex and Astra) and their corresponding list price and AWPs. (BMS3CA/000128).

322. BMS created AWP competitor analyses that tracked the AWPs of its competitors' relevant drugs, and used that date internally to propose suggested AWPs for BMS drugs. One such competitor analysis set forth the competitor AWPs for Atenolol with chlorthalidone and provided an "Apothecon suggested AWP" for each dosage. (BMS3CA/000648)

323. BMS clearly believed that the maintenance of a spread on its drugs was important in gaining and maintaining market share. In an internal BMS document, concerning its drug Vepacid (etoposide), BMS noted:

> The Etopophos product file is significantly superior to that of etoposide injection . . . . Currently, physician practice can take advantage of the growing disparity between Vepesid's list price (and, subsequently, the Average Wholesale Price) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished.

4. Specific BMS AWPs Documented by the DOJ

324. In a report published by the DHHS, the DOJ documented numerous instances where the published AWPs for various dosages of five (5) drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the BMS Group drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by the BMS Group in the 2001 *Red Book*.

Drug	Manufacturer	BMS's 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Amikacin Sulfate	Apothecon	$32.89	$17.31	$15.58	90%
Amphotercin B	Apothecon	$17.84	$6.20	$11.64	188%
Bleomycin Sulfate	BMS	$609.20	$509.29	$99.91	20%
Cyclophospamide	BMS	$102.89	$45.83	$57.06	125%
Etoposide (Vepesid)	BMS	$136.49	$34.30	$102.19	298%

325. Other sources reveal additional evidence of fraudulent AWPs for drugs manufactured and marketed by the BMS Group:

5. Other AWPs Related to VEPESID (etoposide)

326. The February 27, 2001 letter from Rep. Stark to BMS noted that as to BMS ". . . the manipulated discrepancies between [BMS's] inflated AWPs and DPs versus their true costs are staggering. For example, in the 2000 edition of the *Red Book*, Bristol reported an AWP of $1296.64 for . . . Vepesid (Etoposide) for injection . . . while Bristol was actually offering to sell the exact same drug to [a large national group purchasing organization] for $70.00." The difference noted by Rep. Stark represents a % 1,752 spread related to Vepecid.

6. Other AWPs Related to Blenoxane

327. BMS internal documents reveal that in 1995, BMS set the *Red Book* AWP for Blenoxane at $276.29. At the same time, BMS was selling Blenoxane to oncologists practicing in St. Petersburg, Florida for only $224.22. In 1996, BMS increased its reported AWP for

Blenoxane to $291.49, while continuing to sell the drug to oncologist for $224.27. In 1997, BMS falsely reported that it had increased the AWP of Blenoxane to $304.60, when in reality, BMS had lowered the price to oncologists to $155.00. In 1998, BMS again reported a false AWP for Blenoxane of $304.60 while further reducing the actual price to oncologists to $140.00.

7. The BMS Group Provided Free Goods and Other Incentives

328. As part of its scheme the BMS Group also used free drugs and other goods to encourage participation by physicians. Thus, for example, the BMS Group provided free Etopophos® to two Miami oncologists in exchange for their agreement to purchase other BMS Group cancer drugs. Similarly, other documents show that the BMS Group provided free Cytogards in order to create a lower-than-invoice cost to physicians that purchased other cancer drugs through OTN. (A Cytogard is a device that prevents spillage of intravenous administered treatments such as BMS's cancer drug Etopophos®.)

329. As set forth above, the BMS Group's scheme to inflate its reported AWPs, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

330. For example, in a report published by DHHS, the DOJ documented at least 12 instances where the published AWPs for drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers.

331. The chart below sets forth five examples where the BMS Group deliberately inflated AWPs that it reported for BMS Group drugs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by the BMS Group in the 2001 *Red Book*.

Drug	**Manufacturer**	**BMS's 2001 *Red Book* AWP**	**DOJ Determined Actual AWP**	**Difference**	**Percentage Spread**
Amikacin Sulfate	Apothecon	$32.89	$17.31	$15.58	90%
Amphotercin B	Apothecon	$17.84	$6.20	$11.64	188%

Bleomycin Sulfate	BMS	$609.20	$509.29	$99.91	20%
Cyclophospamide	BMS	$102.89	$45.83	$57.06	125%
Etoposide (Vepesid)	BMS	$136.49	$34.30	$102.19	298%

332. In 1997, an OIG Report identified three other Medicare Part B drugs with inflated AWPs – which the 1997 *Red Book* indicates were manufactured only by the BMS Group at that time: Paraplatin® (carboplatin), Rubet® (doxorubicin hydrochloride), and Taxol® (paclitaxel). Sales of these inflated drugs were substantial. For example, Paclitaxel generated $941 million in revenue for the BMS Group in 1997, and Carboplatin generated $702 million in revenue in 2001.

333. The government's investigation uncovered other drugs for which the BMS Group was stating a fraudulent AWP. Specifically:

a. In the 2000 edition of the *Red Book*, BMS reported an AWP of $1296.64 for Vepesid (Etoposide) for injection while BMS was actually offering to sell the exact same drug to a large customer for only $70.00.

b. From 1995 through 1998 the *Red Book* listed AWP for BMS' Blenoxane 15u increased from $276.29 to $304.60, while the actual cost to physicians declined from $224.22 to $140.00, resulting in a spread of $164.60 in 1998

334. An internal BMS Group document shows that the AWP set by the BMS Group for its drugs bears no relation to an ***actual*** wholesale price, and is greater than the highest price actually paid by providers. More specifically, in a discussion about lowering Vepesid's AWP in order to create sales for Etopophos, the BMS Group stated that the "AWP for Vepesid would be reduced from its current level to the highest bid price currently in the marketplace."

335. BMS Group documents also reveal that physicians were making medical decisions based on how much profit they could make from the AWP manipulated spread. In considering provider choice between BMS drugs Etopophos® and Vepesid® (Etoposide), the BMS Group noted that:

> The Etopophos product file is significantly superior to that of etoposide injection . . . . Currently, physician practice can take advantage of the growing disparity between Vepesid's list price (and, subsequently, the Average Wholesale Price) and the actual

> acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished.

336. While the BMS Group and other Defendants have placed the blame for setting published AWPs on the publications in which the AWPs are contained, another BMS Group document demonstrates that publications reporting AWPs had no discretion to set AWPs, and instead published verbatim the prices reported by the BMS Group and other Defendants. In the document, Denise Kaszuba, a senior BMS Group pricing analyst, instructed the *Red Book* that:

> Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%. This change should not effect [*sic*] any other business unit of Bristol-Myers Squibb Company.

H. Dey

337. Dey engages in an organization-wide and deliberate scheme to inflate AWPs. Dey has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Dey for which relief is sought in this case are set forth in Appendix A, and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
DEY		acetylcysteine	Mucolytic (Respiratory Agent: Diagnostic Aid) Used for certain lung conditions when increased amounts of mucus make breathing difficult
		albuterol or albuterol sulfate	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers
		cromolyn sodium	Antiallergic and Mast Cell Stabilizer Used to help prevent or treat the symptoms of seasonal or chronic allergic rhinitis
		ipratropium bromide	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers
		metaproterenol sulfate	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers

1. Dey Has Been the Target of Government Investigations

338. In connection with its scheme to inflate AWPs, Dey has been investigated by the United States Department of Justice, United States Department of Health and Human Services, Office of Inspector General, the United States District Attorney for the District of Massachusetts, the Attorney General of the State of California, the Attorney General for the State of Texas, the Attorney General of the State of Connecticut, and the District Attorney for the County of Suffolk, New York State.

339. These investigations confirm that Dey has engaged in a deliberate scheme to inflate the published AWPs for many of its drugs. For instance, Dey's spread for albuterol sulfate, a drug that constituted 37 % of Dey's income in 1998, drastically increased between 1992 and 1998. In 1992, Dey's *Red Book* AWP for albuterol sulfate (.083% concentration, 3 ml) was $32.30. McKesson's wholesale price for the drug was $25.45 (a spread of $ 6.85 or 27%). By 1998, Dey's *Red Book* AWP for the same concentration/dose of albuterol sulfate had barely slipped to $30.25, while McKesson's wholesale price had plummeted to $10.00 (a spread of $20.25 or 202%). See September 25, 2000 letter from U.S. Rep. Bliley to Nancy-Ann Min DeParle.

340. The federal government is not the only entity to uncover Dey's scheme to inflate AWPs. The Attorneys General of Texas and West Virginia recently discovered that due to over inflated AWPs, both state's Medicaid Programs have been defrauded by Dey for millions of dollars. Texas alleges that, between 1995 and 1999, it paid $13.7 million for Dey's albuterol sulfate and ipratropium bromide, when it should have paid only $8.7 million – an overcharge of $5 million. West Virginia alleges that Dey and others manipulated the AWP to significantly overcharge state agencies and residents for several drugs, including albuterol, from at least 1995 through 2000.

341. In its own suit against Dey and other pharmaceutical manufacturers for AWP manipulation, the Attorney General for the State of Connecticut documented significant spreads

between Dey's published AWPs and actual wholesale prices for many of its drugs. Incorporated below are examples cited by the Connecticut Attorney General:

Drug	NDC #	Year	AWP	ACTUAL PRICE	SPREAD	% OVERCHARGE
ALBUTEROL	49502-0303-17	1996	$21.70	$3.25	$18.45	488%
IPATROPIUM BORMIDE	49502-0685-03	2001	$44.10	$8.35	$35.58	355%
IPATROPIUM BROMIDE	49502-0685-03	2000	$44.10	$11.45	$32.65	239%
IPATROPIUM BROMIDE	49502-0685-03	1999	$44.10	$11.45	$30.11	177%

2. Dey Controls the Published AWP for Its Products

342. Dey has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. Dey's own documents indicate that it initially set both the AWP and WAC for its products and also regularly approved subsequent AWPs and WACs published by industry compendia. For example:

a. In a January 13, 1996 letter from Dey to First Data Bank, Day announced the availability of a new ipratropium bromide inhalation solution. The letter includes the following instructions to First Data Bank:

> "Effective immediately, please update your database to reflect the introduction of this new DEY product as follows:

NDC/ Order Number	Description	Vial Size	Strength	Units per Ctn	Ctns per Case	AWP	WAC
49502-685-03	Ipatropium Bromide Inhalation Solution 2.0%	2.5ml	0.5mg/2.5ml	25	12	**$44.10**	**$25.50**
49502-685-60	Ipatropium Bromide Inhalation Solution 2.0%	2.5ml	0.5mg/2.5ml	60	12	**$105.60**	**$60.90**

(DL-CA00120) (Confidential)

b. In a 1998 worksheet produced by *Red Book* to Dey in order to verify its listings of Dey products, an employee of Dey went through each of the Dey products listed in the *Red Book* and approved each of the AWPs and WACs for each of its products. Handwritten comments on the document include the notation "9/11/98 – checked AWP & WAC pricing (backup attached)" (DL-CA 00080) (Confidential).

3. Dey's AWP Manipulation Benefited Providers at the Expense of the Class

343. The purpose of Dey's AWP manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries. This is clear from Dey's own documents. For example:

a. Dey was aware that its customers were "spread shopping" and competed by increasing the spread to its customers. In an internal worksheet filled out by Dey in preparation for a bid of potential sales to one of its customers, Dey listed the current contract price of various products as well as a recommended new contract price. In the notes next to these figures the worksheet states, "This account needs AWP-40% or better to see profit due to the employer groups they serve. Have not made the switch to our product line due to the spread . . ." (DL-TX-0014029)

b. Competition between generic products produced by Dey was fierce and the spread was a major factor in this competition. In another similar bid price worksheet for a different customer, the corresponding notes state "cromolyn pricing is at AWP-40% and 35% respectively – bear in mind that we are competing with the branded spread and the generic perception of [sic] everything should be AWP-60%" (DL-TX-0014439)

344. This competition came at the expense of Plaintiffs and the Class whose payments were based on AWP. For instance, Albuterol sulfate, a multisource drug and one of Dey's top selling products, was a focus of the federal government's investigation into AWP inflation. OIG found that "Medicare's reimbursement amount for albuterol was nearly six times higher than the

median catalog price" and that "Medicare and its beneficiaries would save between $226 million and $245 million a year if albuterol were reimbursed at prices available to suppliers." *See* "Excessive Medicare Reimbursement for Albuterol," OEI-03-01-00410, March 2002.

345. The OIG determined that the Medicare-allowed amount for albuterol sulfate in 1996 was $0.42. However the actual wholesale price was $0.15, and the highest available wholesale price was $0.21.

346. GAO also found that albuterol sulfate was one of a small number of products that accounted for a large portion of Medicare spending and volume. More specifically, albuterol sulfate ranked first in volume of units covered by Medicare, accounting for 65.8% of total units reimbursed. Furthermore, albuterol sulfate accounted for 6.3% of total Medicare spending, ranking fifth out of more than 400 covered drugs. *See* GAO Report to Congressional Committees, MEDICARE: Payments for Covered Outpatient Drugs Exceed Providers' Cost, Tables 1 and 2, pp. 7-8.

4. Specific Dey AWPs Documented by the DOJ

347. In a report published by the DHHS, the DOJ documented at least 15 instances where the published AWPs for various dosages of 4 drugs manufactured by Dey were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each of the 4 drugs. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Dey in the 2001 *Red Book*.

Drug in Lowest Dosage Form	**2001 *Red Book* AWP**	**DOJ Determined AWP**	**Difference**	**Percentage Spread**
Acetylcysteine	$59.88	$25.80	$34.08	132%
Albuterol Sulfate	$30.25	$9.17	$21.08	230%
Cromolyn Sodium	$42.00	$23.01	$18.99	82%
Metaproterenol Sulfate	$30.75	$11.29	$19.46	172%

5. Inflated Dey AWPs From Dey's Price Lists

348. According to Dey's own documents, the published AWPs for many of its own products were higher than the actual prices charged wholesalers and other intermediaries. Table 1 below is excerpted from a pricing proposal by Dey to McKesson Drug Company, one of the county's largest wholesalers, dated December 20, 1995.

Table 1

Generic Name	Strength	Size	AWP	WAC	Suggested Sell Price	% Discount from WAC	% Spread
Acetylcysteine Solution	10%	4 mL	$67.80	$25.80	$18.00	-40.0%	277%
Acetylcysteine Solution	10%	10 mL	$40.26	$15.27	$13.50	-30.0%	198%
Acetylcysteine Solution	10%	30 mL	$110.48	$41.97	$33.50	-35.0%	230%
Acetylcysteine Solution	20%	4 mL	$81.36	$31.08	$21.50	-40.0%	278%
Acetylcysteine Solution	20%	10 mL	$48.66	$18.57	$16.20	-30.0%	200%
Acetylcysteine Solution	20%	30 mL	$133.43	$50.64	$39.90	-35.0%	234%
Acetylcysteine Solution	20%	100 mL	$92.21	$75.90	$59.90	-40.0%	54%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	$30.25	$14.50	$12.00	-29.3%	152%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	$36.30	$17.40	$14.40	-29.3%	152%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	$72.60	$34.50	$28.80	-28.7%	152%
Cromolyn Sodium Inhalation, USP	20 mg/2ml	2 mL	$42.00	$34.20	$29.00	-25.0%	45%
Cromolyn Sodium Inhalation, USP	20 mg/2ml	2 mL	$84.00	$66.00	$58.00	-22.3%	45%
Metaproterenol Sulfate Inhalation Soln.	0.4%	2.5 mL	$30.75	$11.00	$10.00	-21.5%	207%
Metaproterenol Sulfate Inhalation Soln.	0.6%	2.5 mL	$30.75	$11.00	$10.00	-21.5%	207%
Sodium Chloride Solution	0.9%	3 mL	$24.20	$13.00	$10.94	-32.7%	121%
Sodium Chloride Solution	0.9%	5mL	$24.20	$13.00	$10.94	-32.7%	121%

(DL-TX 0011179)

6. Dey Provided Free Goods and Other Incentives

349. In addition to marketing the spread, Dey has utilized other impermissible inducements to stimulate sales of its drugs without accounting for them in its WAC or AWP. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements,

Dey provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

350. For example, in an announcement of a special incentive program to its customers to induce the purchase of its Ipratropium Bromide Inhalation solution, Dey sent its customers an offer sheet entitled "Profitability Enhancement For You" in which it stated "For every dollar of Dey Cromolyn Sodium unit-dose purchased, Dey will provide free goods of either: Coromolyn Sodium Inhalation Solution 0.02%, 2.5ml, at 1.0 times the rebate amount -OR- Ipatropium Bromide Inhalation Solution 0.02%, 2.5ml, when it launches, at a value of 1.5 times the rebate amount for Cromolyn." (DL-TX-0004775).

7. Dey Has Concealed Its AWP Manipulation

15. In an effort to conceal the existence of a spread from end payors, Dey concealed the true wholesale prices of its drugs. For instance, in a handwritten memorandum to Dey's pricing committee a potential pricing structure with a customer was discussed:

> "I met with IPC to discuss our contract offer (illegible). . . Tom Konnelly (IPC) said he wanted to keep net pricing hidden from 3rd parties by increasing in the purchase price on our offer by 25%. IPC then requires a 25% rebate back to IPC. . . I have remarked the pricing. If this offer is accepted, the higher price will go into McKesson as a chargeback contract. Dey will then rebate IPC 25% on contract purchases on a quarterly basis. . ."

(DL-TX-0024844)

351. As set forth above, Dey's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

I. The Fujisawa Group (Fujisawa Pharmaceutical, Fujisawa Healthcare, Fujisawa USA)

352. Fujisawa engages in an organization-wide and deliberate scheme to inflate AWPs. Fujisawa has stated fraudulent AWPs for all or almost all of its drugs, including those set forth

below. The specific drugs of Fujisawa for which relief is sought in this case are set forth in Appendix A and are identified as follows:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
FUJISAWA GROUP (Fujisawa Healthcare, Fujisawa Pharmaceutical and Fujisawa USA)	Aristocort	triamcinolone, triamcinolone diacetate or triamcinolone acetonide	Anti-Inflammatory, Steroidal; Used in the treatment of asthma
	Aristospan	triamcinolone hexacetonide	Anti-Inflammatory Agent, Steroidal Used to provide relief for inflamed areas of the body
	Cefizox	ceftizoxime sodium or ceftizoxime in d5w	Antibiotic Agent (Anti-Infective Agent) General antibiotic
	Cyclocort	amcinonide	Anti-Inflammatory Agent Used to treat inflammatory symptoms of skin disorders
	Lyphocin	vancomycin hydrochloride	Antibacterial Agent Used to treat infections in many different parts of the body
	Nebupent	pentamidine isothionate	Antiprotozoal Agent Used to try to prevent Pneumocystis carinii pneumonia
	Pentam 300	pentamidine isethionate	Anti-Infective Agent Used in the treatment of pneumonia
	Prograf	tacrolimus	Immunosuppressant Used to lower the body's natural immunity in patients who receive organ transplants
		acyclovir sodium	Antiviral Agent Used to treat herpes simplex infections, varicella-zoster (chickenpox) in people with weakened immune systems, and severe genital herpes infections
		dexamethasone sodium phosphate	Anti-Inflammatory Agent; Antiemetic (Gastrointestinal Agent) Used in various applications to treat inflamed areas of the body
		doxorubicin hydrochloride	Antineoplastic Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma
		fluorouracil	Antineoplastic Used to treat cancer, including colon, rectum, breast, stomach, and pancreas
		gentamicin sulfate	Antibacterial Agent Used to treat serious bacterial infections

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		vinblastine sulfate	Antineoplastic Used in the treatment of various forms of cancer, including lymphoma and breast cancer

1. Fujisawa Has Been the Target of Government Investigations

353. In connection with its scheme to inflate AWPs, Fujisawa has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

2. Fujisawa Controls the Published AWP for Its Products

354. Fujisawa controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, on March 10, 1997, Fujisawa provided MediSpan with an updated listing of pack prices – including AWPs – for all of its products. (FJ-MDL 015152-015159).

3. Fujisawa's AWP Manipulation Benefited Providers at the Expense of the Class

355. The purpose of Fujisawa's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. Fujisawa understood that providers and intermediaries sought significant AWP spreads. In a March 1995 Monthly Report, dated March 30, 1995, Fujisawa noted:

> We have lost our Vanco business at Chartwell. They have recently been handed an edict to order those products with the largest spread between acquisition cost and AWP. Abbott has unbelievably high Vanco AWP. In an effort to counter this loss I suggested we look at picking up the Cefazolin business where our AWP for one gram Cefazolin is over $8. Unfortunately our 10 gram price does not follow the same formula and is in the $45 range while Schein is approximately $58. We do however have a shot at Cefizox for Medicaid/Medicare patients which make up 50% of Chartwell's patients. Medicaid does not reimburse Chartwell for the Rocephin they currently use and while they will not reimburse for Cefizox either they could acquire Cefizox at a

> fraction of the cost. They use $400,000 in Rocephin annually, $200,000 for Medicaid/Medicare patients. That works out to better than $100K in savings for Chartwell.

(FJ-MDL 005687-88) (Confidential).

356. Fujisawa, in a conscious effort to increase the spread for providers and intermediaries, changed its AWPs and marketing practices accordingly. In a May 1995 Monthly Report, dated May 30, 1995, Fujisawa addressed its recent decision to increase its AWP for Vancomycin Hydrochloride and aggressively market the resulting spread increase:

> Many thanks to Rick and Bruce for adjusting the AWP on the five gram Vanco. This should lead to more business. As I have previously reported, some companies are still using AWP for reimbursement purposes. Chartwell has been told to search for the largest spread and order accordingly. I would have liked to see us match Abbott's AWP for our complete Vanco, and Cefazolin line. I will settle for the five gram at $1 below Abbott but that means that we still have to compete at the other end of the equation. For example, if Abbott's AWP is $163 and their contract is $30 and if our AWP is $162 we will have to be at least $29 to have the same spread. Follow?

(FY-MDL 005668-69) (Confidential).

357. In an October 5, 1993 interoffice memorandum discussing Fujisawa's communications with industry pricing compendia, Fujisawa acknowledged that the AWPs for nearly all of its products is inflated at least 33% over direct list prices:

> One of the issues regarding our companies AWP listing is that the databases only use our listing as a "Suggested Manufacturers AWP". The standard wholesaler mark-up used by those databases is currently at 25% above direct list price which is our hospital list. Almost all of our products are at 33% or higher above list price.

(FJ-MDL 008346) (Confidential).

358. Further, just as Fujisawa motivates providers to administer drugs based on the AWP, Fujisawa rewards PBMs based on the degree of influence they exert to drive utilization of Fujisawa products. (FJ-MDL 010272-78) (Confidential).

4. Specific Fujisawa AWPs Documented by the DOJ

359. In a report published by the DHHS (AB-00-86), the DOJ documented at least 35 instances where the published AWPs for various dosages of 6 drugs manufactured by Fujisawa were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 6 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Fujisawa in the 2001 *Red Book*.

Drug	The Fujisawa Group's 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Acyclovir Sodium	$565.10[2]	$371.50	$193.60	52%
Dexamethasone Sodium Phosphate	$1.04[3]	$.66	$.38	58%
Fluorouracil	$2.87	$1.20	$1.67	139%
Gentamacin Sulfate	$12.64[4]	$5.40	$7.24	134%
Pentamidine Isethionate	$98.75	$36.00	$62.75	174%
Vancomycin Hydrochloride	$10.97[5]	$7.00	$3.97	57%

(P006299-006316).

5. Inflated AWPs From Fujisawa Price Lists

360. In response to government subpoenas, Fujisawa produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Fujisawa has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spreads offered to each specific customer here is not practical.

[2] Calculation based on the AWP listed in the 1998 *Red Book*.

[3] Calculation based on the AWP listed in the 1998 *Red Book*.

[4] Calculation based on the AWP listed in the 1998 *Red Book*.

[5] Calculation based on the AWP listed in the 1998 *Red Book*.

361. Set forth below in Table 1, however, are the AWP, contract prices and spread of a number of drugs (not already referenced above) included in a Fujisawa customer price list dated August 24, 1995, and their associated AWP spread. (FJ-MDL 013079-81) (Confidential).

Table 1

Drug	Contract Price	AWP	$ Diff AWP	% Spread
Triamcinolone	$14.33	$17.95	$3.62	25%
Calcium Gluconate	$11.50	$34.00	$22.50	196%
Cefazolin Sodium	$139.00	$367.13	$228.13	164%
Ceftizoxime Sodium	$7.50	$11.86	$4.36	58%
Amcinonide	$41.50	$52.13	$10.63	26%
Doxycycline Hyclate	$15.00	$73.75	$58.75	392%
Fluphenazine Hydrochloride	$24.10	$30.25	$6.15	25%
Folic Acid	$7.25	$11.85	$4.26	63%
Levothyroxine Sodium	$3.90	$38.43	$34.53	885%
Lidocaine Hydrochloride	$17.00	$24.50	$7.50	44%
Magnesium Sulfate	$22.00	$138.25	$116.25	528%
Mannitol	$28.00	$56.50	$28.50	101%
Neostigmine Methylsulfate	$8.20	$89.30	$81.10	989%
Oxytocin	$13.50	$24.50	$11.00	81%
Potassium Acetate	$92.00	$312.40	$220.40	240%
Potassium Chloride	$12.25	$30.50	$18.25	149%
Potassium Phosphate	$30.25	$133.75	$103.50	342%
Pyridoxine Hydrochloride	$35.00	$47.00	$12.00	34%
Scopolamine Hydrobromide	$22.00	$30.00	$8.00	36%
Selenium	$18.25	$195.25	$177.00	970%

362. Set forth below in Table 2, however, are the AWP, contract prices and spread of a number of drugs (not already referenced above) included in a Fujisawa price list dated November 5, 1996, and their associated AWP spread. (FJ-MDL 008240-53) (Confidential).

Table 2

Drug	Wholesaler Price	AWP	$ Diff AWP	% Spread
Adenocard IV	$21.95	$26.34	$4.39	20%

Drug	Wholesaler Price	AWP	$ Diff AWP	% Spread
Adenoscan	$179.00	$223.75	$44.75	25%
Aristocort A	$7.05	$8.46	$1.41	20%
Atropine Sulfate Injection	$.64	$1.12	$.48	75%
Doxorubicin	$12.44	$45.50	$33.06	266%
Furosemide	$.74	$.98	$.24	32%
Hydroxyzine Hydrochloride	$.42	$.65	$.23	55%
Protamine Sulfate	$3.33	$5.32	$1.99	60%
Selepen	$18.24	$29.93	$11.68	64%
Sodium Acetate	$8.81	$14.63	$5.82	66%
Sodium Bicarbonate	$2.04	$3.33	$1.29	63%
Sodium Chloride	$.68	$1.40	$.72	106%
Sodium Phosphate	$5.81	$9.08	$3.27	56%
Tracelyte	$8.26	$11.57	$3.31	40%
Vinblastine Sulfate	$26.50	$43.23	$16.73	63%
Water for Injection	$1.10	$2.34	$1.24	113%

363. As set forth above, Fujisawa's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

J. The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)

364. The GSK Group has engaged in an organization-wide and deliberate scheme to inflate AWPs. The GSK Group has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs manufactured and/or distributed by the GSK Group for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
GSK GROUP (SmithKline	Advair Diskus	salmeterol-fluticasone	Bronchodilator (Respiratory Agent) Used for treatment of asthma
Beecham, GlaxoSmithKline and Glaxo Wellcome)	Agenerase	amprenavir	Antiviral Agent Used in treatment of HIV infection
	Alkeran	melphalan	Antineoplastic Used to treat ovarian cancer and a certain type of cancer in the bone marrow

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Amerge	naratriptan succinate	Antimigraine Agent Used for treatment of migraine attacks
	Beconase AQ	beclomethasone dipropionate monohydrate	Anti-Inflammatory Agent Used to treat discomfort of hay fever, other allergies, and other nasal problems
	Ceftin	cefuroxime axetil	Antibacterial Agent Used to treat infections caused by bacteria
	Combivir	lamivudine-zidovudine	Antiviral Agent Used in treatment of HIV infection
	Daraprim	pyrimethamine	Antiprotozoal Used for treatment of malaria and other protazoal infections
	Epivir	lamivudine	Antiviral Agent Used in treatment of HIV infection
	Flonase	fluticasone propionate (nasal)	Anti-Inflammatory Agent Used for treatment of allergic and nonallergic rhinitis
	Flovent	fluticasone propionate (inh)	Antiasthmatic (Anti-Inflammatory Agent) Used for treatment of asthma
	Imitrex	sumatriptan or sumatriptan succinate	Antimigraine Agent Used for treatment of migraine attacks or cluster headaches
	Kytril	granisetron hcl	Antiemetic (Gastrointestinal Agent) Used to prevent the nausea and vomiting that may occur after chemotherapy
	Lamictal	lamotrigine	Anticonvulsant Used to help control some types of seizures in the treatment of epilepsy
	Lanoxin	digoxin	Antiarrhythmic Agent (Cardiovascular Agent) Used to improve the strength and efficiency of the heart, or to control the rate and rhythm of the heartbeat.
	Leukeran	chlorambucil	Alkylating Agent (Antineoplastic) Used to treat cancer of the blood and lymph system
	Mepron	atovaquone	Antiprotozoal Used to treat and to prevent pneumonia
	Myleran	busulfan	Antineoplastic Used to treat some kinds of cancer of the blood.
	Navelbine	vinorelbine tartrate	Antineoplastic Used for treatment of lung cancer

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Paxil	paroxetine hcl	Antianxiety agent; Antidepressant (Psychotherapeutic Agent) Used in the treatment of various psychotherapeutic disorders
	Purinethol	mercaptopurine	Antimetabolite (Antineoplastic) Used to treat some kinds of cancer.
	Relenza	zanamivir	Antiviral Agent Used in the treatment of the infection caused by the flu virus (influenza A and influenza B).
	Retrovir	zidovudine	Antiviral Agent Used for treatment of HIV infection
	Serevent	salmeterol xinofoate	Bronchodilator (Respiratory Agent) Used to treat or prevent symptoms of asthma, chronic bronchitis, emphysema, and other lung diseases
	Trizivir	abacavir sulfate-lamivudine-zidovudine	Antiviral Agent Used for treatment of HIV-1 infection
	Valtrex	valacyclovir hcl	Antiviral Agent Used for treatment of shingles and genital herpes
	Ventolin HFA	albuterol sulfate	Bronchodilator (Respiratory Agent) Used for treatment or prevention of bronchospasm
	Wellbutrin	bupropion hcl	Antidepressant (Psychotherapeutic Agent) Used for treatment of depression
	Zantac	rantidine hydrochloride	Gastrointestinal Agent Used in the treatment of active duodenal ulcer
	Ziagen	abacavir sulfate	Anti Infective Agent Used in the treatment of HIV infection
	Zofran	ondansetron hcl	Antiemetic (Gastrointestinal Agent) Used to treat or prevent the nausea and vomiting that may occur after chemotherapy
	Zofran ODT	ondansetron	Antiemetic (Gastrointestinal Agent) Used to treat or prevent the nausea and vomiting that may occur after chemotherapy
	Zovirax	acyclovir	Antiviral Agent Used for treatment of shingles, genital herpes and herpes simplex
	Zyban	buproprion hcl	Antidepressant (Psychotherapeutic Agent) Used to relieve mental depression. Also used to aid in cessation of smoking
		thioguanine	Antineoplastic Used to treat some kinds of cancer

1. The GSK Group Has Been the Target of Government Investigations

365. In connection with its scheme to inflate AWPs, the GSK Group has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, the Attorney General for the State of California, and the Attorney General for the State of Nevada, Medicaid Fraud Control Unit.

366. These investigations confirm that the GSK Group has engaged in a deliberate scheme to inflate the published AWPs for its drugs.

2. The GSK Group's Definition and Understanding of AWP

367. In a GSK document entitled "Zofran Tablets & Zofran Injection: Sales Training Guide Reimbursement Module" (GSK-MDL-ZN02-035925) (Highly Confidential), GSK defines AWP as follows:

> Average Wholesale Price (AWP): The composite wholesale prices charged on a specific commodity that is assigned by the drug manufacturer and is listed in either the Red Book or Blue Book and used by third-party payers as a basis for reimbursement.

(GSK-MDL-ZN02-035985) (Highly Confidential). Thus, by its own definition, GSK recognizes that: (i) AWP should be an average of actual wholesale prices; (ii) the drug manufacturers control the published AWP; and (iii) the published AWPs directly affect the payments made by the Class.

3. The GSK Group Controls the Published AWP for Its Products

368. The GSK Group has controlled and set the AWPs for its pharmaceutical products during the Class Period. As set forth below, any claim that The GSK Group only reports a WAC to industry compendia and therefore is not responsible for the published AWPs is belied by its own documents. For example:

a. In 1991 a Glaxo document entitled "Zofran Third Party Payment Plan," among the many recommendations concerning the pricing of its then new drug Zofran was the

recommendation that "In establishing direct-to-wholesaler and *Red Book* wholesale prices for Zofran, Glaxo should take into consideration physicians' expected profit margins." (GSK-MDL-ZN02-03428) (Highly Confidential).

b. Expanding further on the recommendation above, elsewhere in the same document it is stated: "Because insurers often reimburse physician-infused drugs up to the average wholesale price (AWP), the doctor's profits are determined by the differential between the AWP and the price they pay to the wholesaler or pharmacy supplier. The company should ensure that doctors will make acceptable return on Zofran® by managing markups through the distribution chain." (GSK-MDL-ZN02-034366) (Highly Confidential).

369. As do all of the Defendants, GSK has direct control over the "markups" in the distribution chain for its products. That control results from an ability to set the published AWP.

4. The GSK Group's AWP Manipulation Benefited Providers at the Expense of Plaintiffs and the Class

370. GSK acknowledged that the AWP, as published in industry compendia, was used as the basis for most payments by third party payors. GSK's own documents state, "Most, but not all, plans determine a payment for new drugs, based on the drug's cost as listed in the *Red Book* and pay all providers that amount less any patient co-payments." (GSK-MDL-ZN02-035965) (Highly Confidential). Elsewhere in the same document GSK acknowledges: "Payment amounts for most payers is usually based on the AWP as listed in *Red Book*, however, co-payments, especially for Zofran Tablets will be required." (GSK-MDL-ZN02-035973) (Highly Confidential).

371. The purpose of The GSK Group's AWP manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. That scheme has resulted in a system where drugs are administered based upon a profit incentive to physicians and other intermediaries and which results in an incentive to prescribe more expensive, rather than cheaper drugs. In talking points prepared in advance of

negotiations with clinics, Glaxo instructed its sales people to remind customers that "Cheaper is not necessarily a prudent medical or business decision" and that "Cheaper ≠ Good medicine or Good Business!" (GSK-MDL-ZN02-077818-19) (Highly Confidential).

372. The GSK Group tried to maximize spread because it understood that its customers routinely engaged in "spread shopping" – comparing its AWPs with those of its competitors in order to determine the greatest spread (and therefore sell or administer the drug with the greatest spread).

373. Perhaps the most flagrant example of the GSK Group's fraudulent manipulation of AWPs is found in the documents relating to Glaxo's Zofran® and SKB's Kytril®. These two drugs both minimize the nausea associated with chemotherapy, and, prior to the merger of Glaxo and SKB, competed head-to-head in the same market. As detailed below, much of that competition concerned which product could generate ***the greater spread***, or profit, for physicians; not over which product was better for patients.

5. Glaxo's Zofran®

374. A Glaxo marketing document, sent to its sales and marketing personnel via U.S. Mail and interstate wire facilities, advises that they should emphasize to medical providers both the benefits of Zofran® and the financial benefits of the spread. Specifically:

> By using a 32 mg bag, the physician provides the most effective dose to the patient and increases his or her profit by $_____ in reimbursement as well as paying no upcharges for the bag or admixing

375. A follow-up internal Glaxo memo, dated October 27, 1994, entitled "Zofran Pricing Recommendation," states: "Physician reimbursement for the administration of intravenous oncology drugs is based on the spread between acquisition cost and the AWP." The memo later notes that "Kytril carries a 20% spread between List Price and AWP compared to Zofran which carries a 16 2/3% spread providing SKB with a significant advantage in the clinic setting with respect to reimbursement." (P007015-P007490, at P007487-P007490).

376. In response to the larger spread being offered on Kytril, this same internal document discusses several options to increase Zofran's spread "to balance the reimbursement spread which currently exists between Zofran and the market in which it competes. . . ." The pricing options considered for increasing the "spread" for Zofran® included:

Recommendation #1

. 4.5% price increase	$178.97 to $187.02
. Increase AWP	16 2/3% to 20% $214.76 to $233.78 (8.5%)
. 3%Wholesaler Rebate (11/14/94 - 1/31/95)	$187.02 to $172.92 (chargeback) $179.92 to $167.31 (rebate)

377. In an effort to hide the fact that Glaxo was increasing the spread for Zofran®, Glaxo elected to not only increase its AWP and provide rebates, but to also include a small actual price increase. In describing the reason for an increase in the actual selling price, an internal Glaxo document states:

> The recommended multi-tiered modification to current promotion, should also provide an immediate resultant impact to weekly unit sales without being easily intelligible by SKB as to the means by which this was achieved. Thus, providing additional time before a competitive response would be delivered.

378. Glaxo internal documents, however, recognized that as a result of its increasing the spread for Zofran®, SKB would have two options:

Option 1:	Decrease the purchase price of Kytril.
Option 2:	Take a price increase to raise the AWP while maintaining purchase price to generate a higher spread than $52.00.

(P007015-P007490, at P007489-P007490).

379. In order to increase the spread for Zofran®, Glaxo increased the AWP for a 20 ml injection of Zofran® to $233.02 in January of 1995. This was discussed in an October 27, 1994

memo entitled "Zofran Pricing Recommendation" and further discussed at a Glaxo pricing committee meeting on November 4, 1994. (P007015-P007490, at P007487-P007490).

380. In February 1995, the *Florida Infusion Chemo Net* reported that Glaxo was increasing the published AWP for Zofran®, but was specifically offering incentives to lower the actual price offered to medical providers, thereby allowing medical providers to seek reimbursement at inflated prices. Specifically:

> Effective January 3, 1995. Glaxo has increased the acquisition costs of Zofran injection. The new AWP is set at $233.02. However, the company has provided incentives to the market place which will ensure that Zofran price to physicians and clinics will be lower than the contractual price available prior to the increase.

Letter from Bliley, Chairman Commerce Committee to Nancy Min DeParle, Sept. 25, 2000 (P007015-P007490, at P007046).

381. Glaxo was fully aware that the larger spread for its product would be a big selling point. A flier in GSK's possession but produced by wholesaler NSS advertises to physicians that:

Your Zofran™ Deal Just Got Better!!!

(Effective 4:00pm January 9, 1995)

*New AWP $233.02

New Price from NSS

** $161.00 * *

(GSK-MDL-ZN02-034942) (Highly Confidential).

382. In March 1996, Glaxo again increased the AWP for Zofran® by 4.8%. In response, SKB immediately increased the AWP for Kytril by 4.8%. An internal SKB memo, dated March 21, 1996, entitled "Kytril Price Increase," states:

> I recommend a 4.8% price increase effective March 25, 1996 for all Kytril presentations. This is in response to a Glaxo Wellcome price increase of 4.8% for Zofran effective March 8, 1996.

(P007015-P007490, at P007078).

383. In a Glaxo internal memo dated October 25, 1994, entitled "Issue considerations on Zofran pricing strategies," Nancy Pekarek (a communications manager for Glaxo who later became Vice-President of U.S. Corporate Media Relations) recognized the implications of increasing the AWP to create a better spread:

> If Glaxo chooses to increase the NWP and AWP for Zofran in order to increase the amount of Medicaid reimbursement for clinical oncology practices, we must prepare for the potential of a negative reaction from a number of quarters. Some likely responses:
>
> (1) Press: Glaxo's health care reform messages stressed the importance of allowing the marketplace to moderate prices. On the surface, it seems that in response to the entrance of a competitor in the market, Glaxo has actually raised its price on Zofran-perhaps twice in one year. How do we explain that price increase on a drug that is already been cited in the press as one of, if not the most expensive drug on the hospital formulary?
>
> ***If we choose to explain the price increase by explaining the pricing strategy, which we have not done before, then we risk further charges that we are cost shifting to government in an attempt to retain market share.***
>
> (2) Congress: Congress has paid a good deal of attention to pharmaceutical industry pricing practices and is likely to continue doing so in the next session. How do we explain to Congress an 8% increase in the NWP between January and November of 1994, if this policy is implemented this year? How do we explain a single 9% increase in the AWP? ***What arguments can we make to explain to congressional watchdogs that we are cost-shifting at the expense of the government?*** How will this new pricing structure compare with costs in other countries?
>
> (3) ***Private insurers, out-of-pocket payers: These groups, and perhaps others, are likely to incur greater costs as a result of this pricing strategy. How will they be affected? What response do we have for them?***

(GSK-MDL-Z01-05675) (Highly Confidential) (emphasis added).

384. Glaxo also knew that Zofran® products were being marketed based on the spread between the actual cost and the published AWP. For example, when Glaxo introduced the Zofran® premixed IV bag, it used marketing materials which stated:

Convenient
Costs Less Than Vial
Higher AWP
Better Reimbursement

(P007015-007490, at P007243).

385. Other internal Glaxo documents directly compared the "Profit Per Dose" and "Profit as %" and "Profit Per Vial" of Zofran® to Kytril®. These comparisons also identified that in order to increase the spread for Zofran®, Glaxo included "early pay disc" and "rebates" and "incentive."

386. In marketing the new Zofran® premixed IV bag, Glaxo produced and used a document entitled "Profit Maximization – It's In the Bag." This document compared Kytril® to Zofran® based upon its total return of investment (ROI). Specifically, Glaxo's marketing materials including the following chart:

	Cost	AWP	Potential Reimbursement/ Patient	Reimbursement/ Year	ROI
Zofran 32mg bag	$110.41	$195.00	84.59	$13,957,350	76.6%
Kytril 1 mg vial	$102.73	$175.00	72.27	$11,924,000	70.3%

(P007114) (Highly Confidential).

387. Another Glaxo document entitled "Profit Maximization – Continued" reflects how much "Total Revenue Potential" there was for using Zofran® because of the large spread between the cost and reimbursement for various Zofran® products. (P007115) (Highly Confidential).

388. An internal SKB document further acknowledges Glaxo's attempts to use and market the spread and its effects on the Class: